AMAX 200

OPERATION MANUAL

User Software Version 3.1.1A

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Table of Contents

1 INTRODUCTION 1-1

2 ORGANIZATION OF OPERATION MANUAL 2-1

2.1 PICTOGRAMS 2-1
2.2 SECTION DESCRIPTION 2-2

3 SPECIFICATIONS 3-1

4 FEATURES 4-1

4.1 TEST PROGRAMMING 4-1
4.2 PROCESSING 4-1
4.3 DATA ARCHIVING 4-1
4.4 MEASUREMENT MODES 4-1
4.5 CALIBRATION 4-2
4.6 SAMPLE HANDLING 4-2
4.7 REAGENT HANDLING 4-2
4.8 PIPETTING SYSTEM 4-3
4.9 TEMPERATURE CONTROL 4-3
4.10 CUVETTE HANDLING 4-3
4.11 THROUGH-PUT 4-3
4.12 QUALITY CONTROL 4-4

5 PHYSICAL DESCRIPTION 5-1

5.1 OVERVIEW 5-1
5.2 CUVETTE STORAGE CHUTE 5-1
5.3 INCUBATION RAIL AND PROBE WASH WELL 5-2
5.4 ROBOT ARM 5-2
5.5 MEASURING WELLS 5-3
5.6 REAGENT AND SAMPLE TRAY 5-3
5.7 SYRINGE 5-4
5.8 BACK VIEW 5-4

6 GENERAL SOFTWARE USE 6-1

7 POWER ON 7-1

7.1 AMAX 200 7-1
7.2 PERIPHERAL EQUIPMENT 7-1

8 TRAFFIC SIGNAL LIGHTS AND STATUS INDICATOR BAR 8-1

8.1 TRAFFIC LIGHTS 8-1
8.2 STATUS INDICATOR BAR 8-1
8.2.1 Operating Status 8-1
8.2.2 Reagent Level Monitor 8-1
8.2.3 Temperature Monitors 8-2
8.2.4 Lamp Monitor 8-2
8.2.5 Cuvette Box Monitor 8-2
8.2.6 Cuvette Tray Waste Monitor 8-2

8.2.7 Fresh Water Input Monitor 8-2
8.2.8 Waste Water Output Monitor 8-2
8.2.9 Test Group Selection 8-2
8.2.10 Number of Files in Archive 8-2
8.2.11 File Format Date 8-2
8.2.12 QC Status Monitor 8-3
8.2.13 LIS Status Monitor 8-3

9 OPERATION - QUICK-START 9-1
9.1 ENTRY INTO QUICK-START 9-1
9.2 INTRODUCTION TO QUICK-START DIALOG WINDOW 9-3
9.3 TEST GROUP SELECTION 9-3
9.4 ORDERING TESTS 9-4
9.5 REAGENT TRAY PREPARATION 9-6
9.6 PRELIMINARY CHECKS 9-8
9.7 START PROCESSING 9-9
9.8 STOPPING OR ABORTING PROCESSING 9-10
9.9 VIEWING RESULTS 9-11
9.10 ADDING NEW SAMPLES 9-11
9.11 REPLENISHING REAGENTS 9-13
9.12 REPEATING TESTS 9-13
9.13 ADDING STAT SAMPLES 9-14
9.13.1 Stat Sample Deletion 9-15
9.14 PRINTING RESULTS 9-16
9.14.1 Routine samples 9-17
9.14.2 Stat samples 9-17
9.15 STARTING A NEW SAMPLE TRAY 9-18
9.16 CHECKING QC RESULTS 9-18
9.17 OPERATION AND MONITOR FUNCTIONS 9-18
9.17.1 Reagent Overview 9-19
9.17.2 AMAX200 - Status 9-19
9.17.3 Prime 9-20
9.17.4 Wash 9-20
9.17.5 Test Groups 9-20
9.17.6 Check Reagent 9-20
9.17.7 Stop 9-20
9.17.8 Abort 9-20
9.18 EXITING QUICK-START 9-20
ABBREVIATED QUICK-START OPERATING PROCEDURE 9-22

10 OPERATION - NORMAL 10-1
10.1 REAGENT PREPARATION 10-1
10.2 FRESH AND WASTE WATER CHECKS 10-3
10.3 CUVETTE PREPARATION 10-4
10.4 FORMAT DATA FILES 10-6
10.5 SAMPLE IDENTIFICATION, POSITIONING AND TEST REQUISITIONING 10-6
10.5.1 Keyboard Addition of New Patients 10-8

10.5.2 Keyboard Edit of Old Patients 10-10
10.5.3 Position Samples in Sample Tray 10-11
10.6 START PROCESSING 10-11
10.6.1 Select Test Group 10-12
10.6.2 Start 10-12
10.7 PAUSE, STOP AND ABORT 10-15
10.7.1 Pause 10-15
10.7.2 Stop 10-16
10.7.3 Abort 10-16

10.8 STAT TESTING 10-16
10.8.1 Stat Requisitioning 10-16
10.8.2 Viewing and Printing Stat Results 10-17
10.8.3 Emptying Stat Positions and Transferring Sample to Archive 10-17
10.9 OVERVIEW 10-18
10.10 GRAPHIC MODE 10-18
10.11 REPEAT TESTING 10-18
10.12 PRINTOUT OF RESULTS 10-19
10.13 EVALUATION OF QC RESULTS 10-20
10.14 PRINTOUT OF PATIENT REPORTS 10-21
10.15 ERRORS DURING PROCESSING: NON-FATAL 10-21
10.16 ERRORS DURING PROCESSING: FATAL 10-22
10.17 SHUTDOWN 10-23

11 MEASUREMENT PRINCIPLES 11-1
11.1 MECHANICAL MEASUREMENT (BALL METHOD) 11-1
11.2 OPTICAL MEASUREMENT 11-3
11.3 KINETIC OPTICAL MEASUREMENT (CHROMOGENIC) 11-5

12 MENUS OVERVIEW 12-1
12.1 MAIN MENU 12-1
12.2 <ALT>-FUNCTION KEYS 12-3
12.3 <CTRL-F1>-FUNCTION KEYS 12-5
12.4 DOS PARAMETERS 12-5
12.5 MENUS OUTLINE 12-10
12.6 MENUS FLOWCHARTS 12-14

13 OVERVIEW MENU 13-1
13.1 AMAX200 13-1
13.2 REAGENT 13-2
13.3 RESULTS 13-3
13.4 SAMPLES 13-4

14 SERVICE MENU 14-1
14.1 PRIME 14-1
14.2 WASH 14-2
14.3 TRANSFER CUP 14-2

14.4 CHECK REAGENT 14-3
14.5 LAMP OFF/ON 14-3
14.6 CALIBRATE PHOTOMETER 14-4
14.7 MOVE SYRINGE 14-4
14.8 CHECK VOLUMES 14-4
14.9 LOCK CHANNELS 14-4
14.10 MONITOR 14-6

15 MEASURE MENU 15-1
15.1 TEST GROUPS 15-1
15.2 TRAYS 15-2
15.2.1 Show 15-4
15.2.2 Delete 15-4
15.2.3 Load 15-5
15.2.4 Load Auto 15-6
15.3 ROBOT RIGHT 15-6
15.4 START 15-6
15.5 GRAPHIC 15-12
15.6 PAUSE, STOP AND ABORT 15-14
15.6.1 Pause 15-14
15.6.2 Stop 15-15
15.6.3 Abort 15-15

16 STAT MENU 16-1
16.1 QUICK-START 16-1
16.2 STAT POSITION 1 - 8 16-1
16.2.1 Stat Requisitioning 16-2
16.3 MONITORING AND PRINTING STAT RESULTS 16-4
16.4 EMPTYING STAT POSITIONS AND TRANSFERRING DATA TO ARCHIVE 16-4
16.5 END 16-5

17 PATIENTS MENU 17-1
17.1 NEW 17-1
17.2 EDIT 17-5
17.3 ADD 17-7
17.4 REPEAT 17-10
17.5 IMPORT 17-12
17.6 EXPORT 17-12
17.7 PATIENT LIST 17-13
17.8 RESULT LIST 17-13
17.9 RESULTS LIST ON-LINE 17-15
17.10 REPORT 17-15

18 SYSTEM MENU 1 18-1
18.1 FORMAT DATA FILES 18-1
18.2 SECURITY SYSTEMS: PASSWORD, SIGN ON, OR SET USER PIN 18-2
18.2.1 Password 18-3

18.2.2 Sign ON 18-4
18.2.3 Set User PIN 18-4
18.2.3.1 Add an Operator 18-5
18.2.3.2 Signing On 18-6
18.2.3.3 Delete an Operator 18-7
18.2.3.4 To Edit PIN Information 18-7
18.2.3.5 Forgotten Password 18-8
18.3 DRIVE 18-8
18.4 OPTIONS 18-9
18.5 HOST PARAMETERS 18-11
18.6 LOCATION CODES 18-11
18.7 PANELS 18-12
18.8 REPORT FORMAT 18-13
18.8.1 To Design the Report Format 18-13
18.8.2 Error Code Definition 18-14
18.9 VERSION 18-15

19 SYSTEM MENU 2 - PARAMETERS 19-1
19.1 TEST GROUPS 19-2
19.1.1 To Define or Modify a Test Group 19-3
19.1.2 To Delete a Defined Test Group 19-5
19.2 TESTS 19-5
19.2.1 To Define a New Test 19-6
19.2.1.1 Description 19-7
19.2.1.2 Calibration 19-7
19.2.1.3 Procedure 19-10
19.2.1.4 Data reduction 19-11
19.2.1.5 Statistics 19-12
19.2.2 Undo Test Parameter Definition 19-13
19.2.3 Exiting Test Parameter Definition 19-13
19.2.4 Saving Test Parameter Definition 19-13
19.2.5 Copy Test Parameter Definition from One Test to Another 19-14
19.2.6 To Delete a Test from the Test List 19-14
19.2.7 Predilution Mode 19-14
19.2.8 Derived Fibrinogen 19-15
19.3 REAGENT LAYOUT 19-16
19.3.1 To Define or Modify a Reagent Layout 19-17
19.3.2 To Delete a Previously Defined Layout 19-18
19.4 REAGENT 19-18
19.4.1 To Define a New Reagent or Modify a Previously Defined Reagent 19-19
19.4.2 To Delete a Reagent 19-20
19.5 LEVELS 19-20
19.5.1 Diameter 19-21
19.5.2 Bottom Levels 19-22
19.5.3 Maximum Level 19-23
19.5.4 Predilution Levels 19-23
19.6 PUMP 19-24
19.7 MEASURING MODE 19-25
19.8 TEMPERATURE 19-28

19.9 BACK UP 19-29
19.10 RESTORE 19-29
19.10.1 To Restore a Back Up File 19-30
19.10.2 To Activate the Back Up Parameters 19-31

20 QUALITY CONTROL MENU 20-1

20.1 QC SETUP 20-4
20.1.1 Westgard Definitions 20-4
20.1.1.1 Rule 20-5
20.1.1.2 Enabled 20-5
20.1.1.3 Alarm 20-7
20.1.1.4 Option 20-7
20.1.1.5 Flowchart of Information Transfer 20-9
20.1.2 Controls 20-10
20.1.2.1 Addition of a New Control 20-10
20.1.2.2 To Modify a Previously Defined Control 20-13
20.1.2.3 To Delete a Control 20-15
20.1.2.4 Flowchart of Information Transfer 20-16
20.2 QC FILES 20-17
20.2.1 Create 20-17
20.2.1.1 On an Inactive Test 20-18
20.2.1.2 On an Active Test 20-19
20.2.1.3 On an Undefined or Partially Defined Test 20-19
20.2.1.4 Reactivation of Previously Closed Files 20-19
20.2.2 List 20-21
20.2.3 Export 20-22
20.2.4 Backup 20-22
20.2.5 Restore 20-23
20.2.6 Delete 20-24
20.2.7 Flowchart of Information Transfer. 20-25
20.3 QC CHARTS 20-26
20.3.1 Thumbnail Charts 20-27
20.3.2 Zoom Chart 20-29
20.3.2.1 Introduction 20-29
20.3.2.2 Commands 20-30
20.3.2.3 Mean30/Mean 20-33
20.3.2.4 Comment on a Data Point 20-33
20.3.2.5 Omit a Data Point. 20-34
20.3.2.6 Append a File 20-35
20.3.2.7 Change the Target Value 20-36
20.3.2.8 New File 20-36
20.3.3 Z-Score Distribution Chart 20-37
20.3.4 Print QC Report 20-37
20.4 RULE SENSITIVITY SETTINGS 20-39
20.5 VIOLATION EXAMPLES 20-41
20.6 DISTRIBUTION 20-45
20.6.1 Distribution Chart and Report 20-45
20.7 CALIBRATION CURVES 20-46
20.8 REFERENCES 20-47

Table of Contents

21 END MENU 21-1
21.1 REMOVE STAT SAMPLES 21-1
21.2 HOST STATUS 21-1
21.3 PRINTER BUFFER 21-2
21.4 DOS SCREEN 21-2

22 CALIBRATION 21-1
22.1 AUTOMATIC DILUTION 22-1
22.2 MANUAL DILUTION 22-5
22.3 SINGLE-POINT CALIBRATION 22-6
22.4 DERIVED FIBRINOGEN 22-6

23 MAINTENANCE 23-1
23.1 SERVICE OUTLINE 23-1
23.2 DAILY MAINTENANCE 23-3
23.2.1 Clean Probe Exterior 23-3
23.2.2 Fresh Water Check 23-3
23.2.3 Waste Fluid Disposal 23-4
23.2.4 System Wash 23-4
23.2.5 Hydraulic System Leak Check 23-5
23.2.6 Used Cuvette Disposal 23-5
23.2.7 Cuvette Cassette Disposal Area Check 23-5
23.2.8 General Housekeeping 23-6
23.3 WEEKLY MAINTENANCE 23-7
23.3.1 Hydraulic System Cleaning 23-7
23.3.2 Dust Filter Cleaning 23-8
23.3.3 Incubation Rail and Wash/Rinse Well Cleaning 23-8
23.3.3 Coolant Level Check 23-9
23.4 MONTHLY MAINTENANCE 23-10
23.4.1 Syringe Cleaning 23-10
23.4.2 Cleaning of Photometric Measuring Wells 23-10
23.5 MISCELLANEOUS UNSCHEDULED MAINTENANCE 23-11
23.5.1 Photometer Calibration 23-11
23.5.2 Volume Check 23-13
23.6 REPLACEMENT PROCEDURES 23-14
23.6.1 Photometer Lamp 23-14
23.6.2 Syringe/Plunger Assembly 23-15
23.6.3 Syringe Plunger Tip and O-Ring 23-15
23.6.4 Tubing 23-16

24 QUALITY ASSURANCE 24-1
24.1 PATIENT SAMPLE 24-1
24.2 REAGENTS 24-1
24.3 INSTRUMENT MECHANICS 24-1
24.4 TEST PARAMETERS 24-2
24.5 MEASUREMENT ANALYSIS 24-2
24.6 RESULTS 24-2

25 TROUBLESHOOTING 25-1
25.1 NON-FATAL ERRORS 25-1
25.2 FATAL ERRORS 25-1
25.3 GENERAL TROUBLESHOOTING 25-3

26 INSTALLATION 26-1
26.1 INSTALLATION 26-1
26.2 LOCATION REQUIREMENTS 26-1
26.3 ELECTRICAL REQUIREMENTS AND PRECAUTIONS 26-1
26.4 REMOVAL OF SHIPPING SAFETY CLAMPS 26-2
26.5 FRESH WATER AND DRAIN CONNECTIONS 26-2
26.6 POWER ON 26-2

27 INTERFACE SPECIFICATIONS 27-1
27.1 MODES 27-1
27.2 BI-DIRECTIONAL INTERFACE DESCRIPTION 27-1
27.3 PROTOCOL 27-3
27.3.1 MASTER to SLAVE 27-3
27.3.2 SLAVE to MASTER 27-4
27.4 COMMAND CHARACTERS AND SYMBOLS 27-5
27.5 TIMEOUT 27-5
27.6 REPEAT AFTER <NACK> 27-5
27.7 EXAMPLES (AMAX AS MASTER) 27-6
27.8 EXAMPLE OF HEADER AND TEST ORDER 27-10

1 INTRODUCTION 1-1

Introduction

1

The AMAX 200 is an automated random access multi-purpose analyzer. The AMAX 200 may be used as a coagulation analyzer for the detection of fibrin formation utilizing either mechanical principles (ball method) or photo-optical principles.

Such tests include prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen concentration, thrombin time (TT), functional factor assays and other clotting tests ending with fibrin formation. In addition, the AMAX 200 may be used for chromogenic kinetic enzyme analysis (405nm). Such tests include antithrombin (AT), protein C, protein S, antiplasmin, heparin, plasminogen, PAI-1, tPA and other assays utilizing an indicator molecule detected at 405 nm. Measurement may be qualitative or quantitative. When used in conjunction with appropriate reagents, the sample may be plasma, serum or whole blood.

The AMAX 200 is PC controlled. To provide optimum performance and maximum versatility, the operating parameters for each test are individually programmed.

Patient samples are identified by the commander PC and registered in a patient file. With the use of the on-board barcode reader, patient identification is positive. Patient demographic and result information is archived for subsequent retrieval. Both the results and the correlated calculations are stored in the patient file. Information may be transferred to and from a host computer through a bi-directional interface.

The sample storage area is cooled to approximately 15°C. which minimizes sample deterioration and prevents spontaneous cold activation that may occur at colder temperatures. Sampling may be from primary tubes or secondary transfer tubes. Sample and reagent are added using a temperature-controlled probe. All incubation times are programmable. The programmed volume of reagent is added at the programmed time. With addition of the start reagent, either the elapsed time or absorbency is measured.

The measured results are calculated into concentration or activity units with the use of stored calibration curves.

On-line, real-time statistical analysis and evaluation of QC data assists in determining if results are valid and patient results may be reported.

Waste disposal is automatic with minimal operator contact with potentially biohazardous materials.

3 SPECIFICATIONS 3-1

AMAX 200 Dimensions

• Height	25 inches (64 cm)
• Width	32¾ inches (83 cm)
• Depth	28¾ inches (73 cm)

Keyboard

• Height	ca. 1¼ inches (3 cm)
• Width	ca. 11 inches (28 cm)
• Depth	ca. 5¼ inches (13 cm)

Printer

• Height	ca. 10 inches (25 cm)
• Width	ca. 13¾ inches (34 cm)
• Depth	ca. 22 inches (55 cm)

Optional Base Unit Dimensions

• Height	28¼ inches (71 cm)
• Width	32¾ inches (82 cm)
• Depth	27¾ inches (69 cm)

Weight

• AMAX 200	286 pounds (130 kg)
• Base Unit	165 pounds (75 kg)

Electrical

• Voltage	90 - 132 VAC; 60 Hz 180 - 265 VAC; 50 Hz
• Power Consumption	600 VA
• Fuse Requirements	5A (t) 6.3x32 and 10A (t) 6.3x32

Room Temperature Requirements

• Maximum Operating Temperature	90°F (32°C)
• Compensation Required	2047 BT

4 FEATURES 4-1
4.1 TEST PROGRAMMING 4-1
4.2 PROCESSING 4-1
4.3 DATA ARCHIVING 4-1
4.4 MEASUREMENT MODES 4-1
4.5 CALIBRATION 4-2
4.6 SAMPLE HANDLING 4-2
4.7 REAGENT HANDLING 4-2
4.8 PIPETTING SYSTEM 4-3
4.9 TEMPERATURE CONTROL 4-3
4.10 CUVETTE HANDLING 4-3
4.11 THROUGH-PUT 4-3
4.12 QUALITY CONTROL 4-4

4.1 Test Programming

- Up to 32 tests may be programmed at one time
- All sample and reagent volumes, incubation times, reagent addition times and measurement times are programmable to provide maximum flexibility and optimum test performance

4.2 Processing

- Random access; multi-tasking
- Process mechanical, optical and chromogenic tests simultaneously
- Choice of two operating modes: normal and quick-start
- Normal mode: up to 12 tests processed simultaneously using multiple screens to provide for maximum operating flexibility
- Quick start: up to 8 tests processed simultaneously with all operations performed using one screen

4.3 Data Archiving

- Up to 1,020 patients may be archived on commander PC hard drive
- Optional storage of patient data archive on floppy discs
- Patient demographic, value results and correlating calculation information is stored in the archive. With graphic mode on, graphic representation of each reaction is also stored in the archive

4.4 Measurement Modes

- Photo-optical/chromogenic: 4 channels, 405 nm
- Mechanical: 4 channels
- Minimum reaction volume, mechanical: 75 µL
- Minimum reaction volume, optical/chromogenic: 150 µL
- Maximum reaction volume, all modes: 600 µL
- Programmable mechanical impulse mode minimizes break-up of fragile fibrin clots
- Simultaneous mechanical, photo-optical and chromogenic analysis
- Real-time graphic reaction display for optical and chromogenic kinetic analyses
- 28 clotting measuring modes; 16 chromogenic measuring modes
- Monitor available to observe the performance of individual measuring wells
- Channel locking to remove selected measuring wells from service facilitates troubleshooting and minimizes downtime by enabling continuation of processing in the event of isolated channel component failure

4.5 Calibration

- 1 to 8 calibration curve points
- Automatic dilution at any desired dilution from 1:1 to approximately 1:14,000
- Calculation and display of correlation coefficient for each curve
- Dilution of calibration reference material either automatically or with previously prepared dilutions
- Choice of 10 curve calculation types
- Graphic display of calibration curve for easy visual evaluation
- Ability to recalculate curve data using multiple curve calculation types

4.6 Sample Handling

- Cooled (15 ± 3°C) sample storage area with 60 position continuous-addition sample tray
- Up to 8 samples at one time may be processed as Stats
- Up to 17 sample trays with up to 60 samples each may be prepared for processing (1,020 samples) in a file format period
- 5 µL minimum sample volume
- Choice of duplicate or single sampling for each test within a test group
- Automatic sample predilution at any desired dilution from 1:1 to 1:100
- Automatic dilution to either a higher or lower dilution when result exceeds calibration curve limits
- Automatic repeat at a programmable extended time interval for samples failing to clot within the specified measurement time
- Integrated bar code scanner provides capability for positive patient ID
- Optional off-line bar code scanner provides capability for alternative patient ID entry

4.7 Reagent Handling

- Cooled (15 ± 3°C) reagent storage area with 24 position reagent tray; 16 used only for reagent storage, 8 used for either reagent storage or as Stat sample positions
- 3 stir-bar positions
- Up to 50 reagents may be defined
- Operator notification of expired reagents
- Up to 5 reagents may be programmed for each test
- Up to 12 different reagent tray layouts may be programmed
- Minimum reagent levels required prior to and during processing are programmable; reagent levels are continuously monitored and may be refilled with no processing interruption; audible alarm notifies operator of low reagent volume condition
- Reagent container dead volume dependent on container size and on the programmed bottom level sense
- No tubing; direct probe reagent aspiration results in no reagent waste and minimal daily maintenance

4.8 Pipetting System

- Samples and reagents are transferred to the reaction cuvette with a temperature-controlled probe (37 ± 0.5°C)
- Liquid level sensor for both sample and reagent
- Bottom level sensing programmable to any depth for both sample and reagent positions
- Cleaning of probe programmable for each reagent

4.9 Temperature Control

- Reagent/Sample trays: 15 ± 3°C
- Incubation rail: 37 ± 0.5°C
- Probe: 37 ± 0.5°C
- Optical measuring wells: 37 ± 0.5°C
- Mechanical measuring wells: 37 ± 0.5°C
- Continuous monitoring and display of temperatures
- Temperature warning and stop limits are programmable. Audible alarm and flashing display when temperature is out of the warning limit range. Program stop if temperature condition is out of the stop limit range and is not corrected within a specified time period

4.10 Cuvette Handling

- 450 on-board cuvette capacity with continuous refill without processing interruption
- Automatic disposal of cuvettes through measuring wells at completion of measurement timing
- Maximum cuvette utilization

4.11 Through-Put

- Variable; dependent on test combination, programming and sample conditions
- Typical through-put:

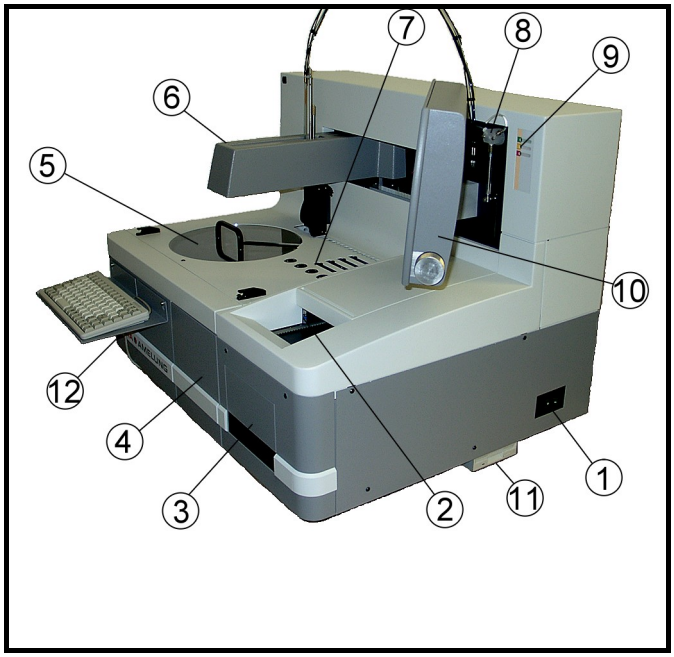
	Tests/Hour	Patients/Hour Single	Patients/Hour Duplicate
PT-Mechanical (Pipette mode 0)	180	180	90
PT-Mechanical (Pipette mode 2)	240	240	120
PT-Optical (Pipette mode 0)	190	190	95
PT-Optical, Derived Fibrinogen	120	120	60
APTT-Mechanical or Optical	110	110	55
Fibrinogen	115	115	57
AT	80	80	40
Factor Assay	120	120	60
PT-Mechanical/APTT	120	60	30
PT-Mechanical/APTT/AT	90	30	15

4.12 Quality Control

- Unlimited number of control files
- 1000 result positions per control level file
- Levey-Jennings-like graphic representation of up to 1000 results on each control for each test programmed
- Zoom chart feature to view specific details including historical rule violations and operator-entered comments; each data point has associated result, date measured, time measured, operator logged on when result processed, Westgard rule evaluation and audit trail for point omission information available
- Any data point may be omitted after user ID and comment are entered
- Optional user ID system with four authorization levels available
- Multiple breakdown (last 30 results, all results, all results up to cursor position) of statistical data
- Laboratory defined operator alert conditions with QC error
- Real-time performance monitor
- Westgard Rules or other laboratory definable result criteria evaluation
- Optional processing stop in event of a QC error
- QC File backup and restore functions available

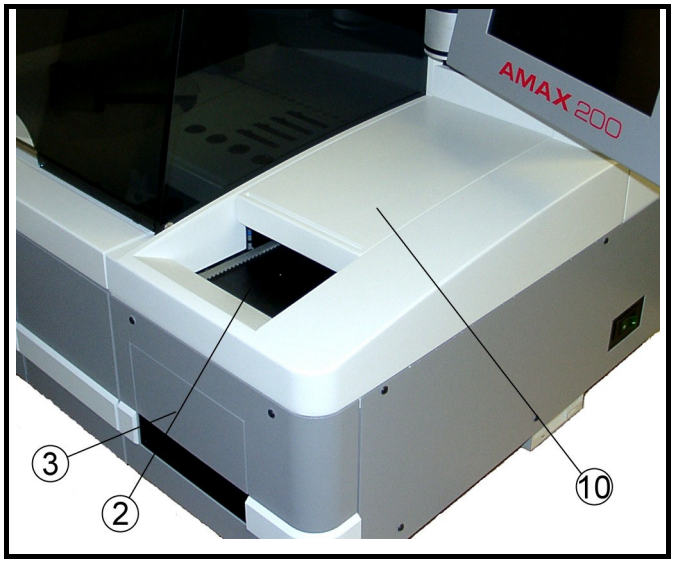
5 PHYSICAL DESCRIPTION 5-1
5.1 OVERVIEW 5-1
5.2 CUVETTE STORAGE CHUTE 5-1
5.3 INCUBATION RAIL AND PROBE WASH WELL 5-2
5.4 ROBOT ARM 5-2
5.5 MEASURING WELLS 5-3
5.6 REAGENT AND SAMPLE TRAY 5-3
5.7 SYRINGE 5-4
5.8 BACK VIEW 5-4

5.1 Overview



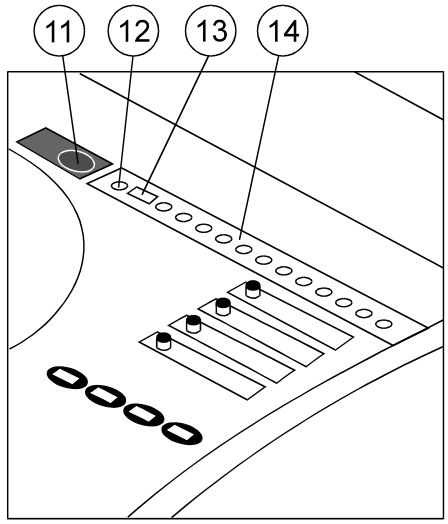
1. Power Switch
2. Cuvette Storage Chute
3. Empty Cuvette Box Disposal Area
4. Cuvette Waste Drawer
5. Reagent/Sample Tray Area
6. Robot Arm
7. Measuring Wells
8. Syringe
9. Status Signal Lamps
10. Monitor
11. Floppy Drive
12. Keyboard Tray

5.2 Cuvette Storage Chute



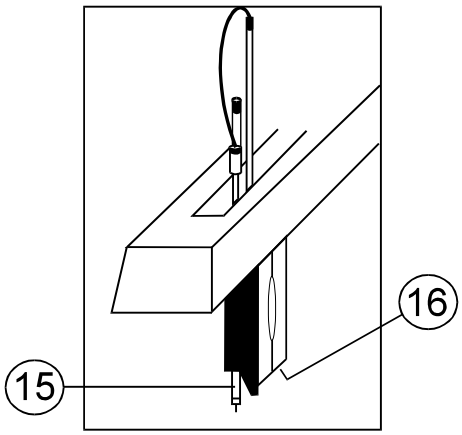
2. Cuvette Chute, Loading Area For New Cuvette Boxes
3. Empty Cuvette Boxes Disposal Area
10. Cuvette Storage Chute Cover

5.3 Incubation Rail and Probe Wash Well



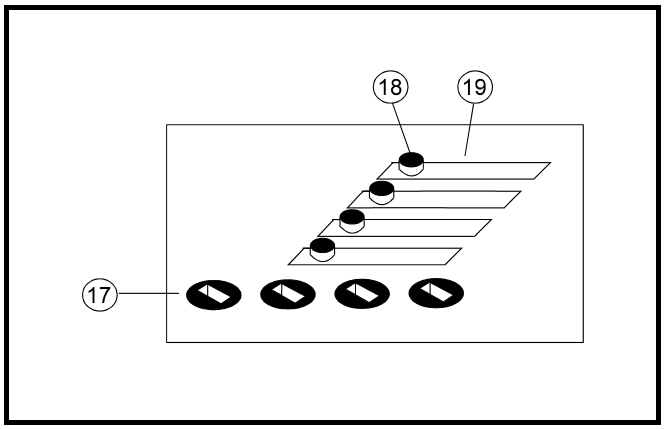
11. Container For Decontaminating Solution
12. Probe Wash Well
13. Cuvette Transfer Position
14. Incubation Rail

5.4 Robot Arm



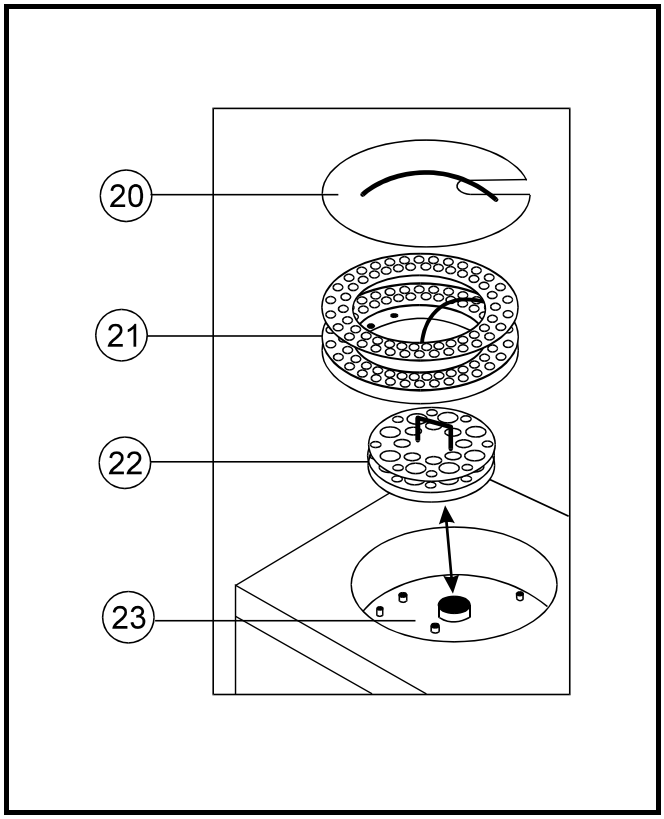
15. Temperature Controlled Probe
16. Cuvette Removal and Transfer Mechanism

5.5 Measuring Wells



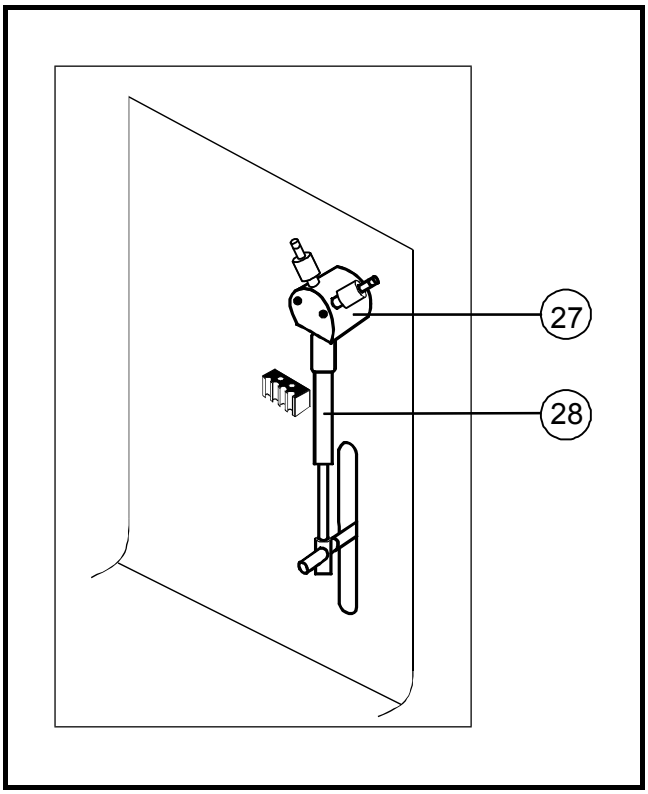
17. Mechanical Measuring Wells
18. Cover Knob
19. Optical Measuring Wells

5.6 Reagent and Sample Tray



20. Cover
21. Sample Tray
22. Reagent Tray
23. Reagent/Sample Tray Well

5.7 Syringe



27. Valve
28. Syringe

5.8 Back View

29. PC Computer Socket
30. Power Socket
31. Fresh Water Level Sensor Connector
32. Fresh Water Inlet Connector
33. Drain Outlet
34. Drain Level Sensor Connector
35. Internal PC

6 GENERAL SOFTWARE USE..... 6-1

General Software Use

Unless otherwise specified, all user interface instructions and screen descriptions are for AMAX software version 3.1.1A.

Instructions are presented using conventional software terms. “Type” means use the keyboard to type in information. “Press” means press the specified key.

Execution actions are in bold and enclosed by **< >**. For example: When the operator action required is to press the “Enter” Key, the action is represented as **<Enter>**.

If simultaneous depression of two keys is required, both keys will be indicated, separated by a hyphen and enclosed by **< >**. For example: When the operator action required is to press both the “Alt” Key and the “F2” Key, the action is represented as **<Alt-F2>**.

Menus and submenus may be selected either by moving the **<Cursor Keys>** to the desired menu/submenu followed by **<Enter>** or by pressing the color-coded letter of the desired menu/submenu.

Move through dialog windows using the **<Cursor Keys>**. Make appropriate entries utilizing either the keyboard or **<Function Keys>**. Help information for the dialog window appears in the first line at the top of the screen. Active **<Function Keys>** for that dialog window are indicated in the second line on the screen. How to exit from the screen is displayed at the bottom of the dialog window.

Most dialog windows are presented as examples. Because the display of the various windows is conditional on events, the exact sequencing of window displays may vary.

When the AMAX 200 is in “Ready” mode, a screen saver will activate after 5 minutes of inactivity. Press any key to return to the menu screen.

When the AMAX 200 is in “Busy” mode, an audible alarm will alert the operator to situations that may require operator attention or to instrument malfunctions. Pressing **<Alt-F2>** will silence the alarm.

7 POWER ON 7-1
7.1 AMAX 200 7-1
7.2 PERIPHERAL EQUIPMENT 7-1

7.1 AMAX 200

Power up the AMAX 200 by pressing the power supply switch from OFF to ON.

The switch is located on the lower back corner of the right side of the instrument.

The switch lights up green when power to the instrument is ON.

WARNING!
Do not switch OFF and ON rapidly. Wait 10–15 seconds after switching OFF before switching ON.

At power ON, the robot arm and the Reagent/Sample Trays (if positioned in the well) move to the home position.

7.2 Peripheral Equipment

Two minutes after the AMAX 200 is powered ON, the PC components may be turned ON. Switch printer, monitor and PC to ON.

The Main Menu of the AMAX 200 Operating Program will be displayed on the monitor screen.

The PC and other peripheral equipment are considered to be an integral part of the AMAX 200 and are dedicated to the operation of the system. The addition of any other software programs (including screen savers) will seriously compromise the operation and reliability of the AMAX 200.

WARNING!
Under no circumstances should any software other than that authorized by Sigma-Amelung GmbH be installed on the PC provided for operation of the AMAX 200.

8. TRAFFIC SIGNAL LIGHTS AND STATUS INDICATOR BAR 8-1
8.1 TRAFFIC LIGHTS 8-1
8.2 STATUS INDICATOR BAR 8-1
8.2.1 Operating Status 8-1
8.2.2 Reagent Level Monitor 8-1
8.2.3 Temperature Monitors 8-2
8.2.4 Lamp Monitor 8-2
8.2.5 Cuvette Box Monitor 8-2
8.2.6 Cuvette Tray Waste Monitor 8-2
8.2.7 Fresh Water Input Monitor 8-2
8.2.8 Waste Water Output Monitor 8-2
8.2.9 Test Group Selection 8-2
8.2.10 Number of Files in Archive 8-2
8.2.11 File Format Date 8-2
8.2.12 QC Status Monitor 8-3
8.2.13 LIS Status Monitor 8-3

8.1 Traffic Lights

The signal lights are located on the upper right-hand corner of the front panel. The status of the instrument may be observed from a distance by the following light patterns:

1. No lighted areas indicate that the instrument is not processing and there are no error area conditions.
2. Green area lit (Go light) indicates that the instrument is processing and there are no error conditions.
3. Yellow area lit (Caution light) indicates that a condition requiring operator attention exists. Condition at this point in time is not of sufficient gravity to stop processing. Error condition will be displayed in a red field in the status area at the bottom of the main menu.
4. Red area lit (Stop light) indicates that a serious unrecoverable error condition has been detected. If processing, the run has been aborted. Follow directions displayed in red at the top of the monitor screen.
5. Sequential flashing lights indicate that a serious error has occurred and the instrument is undergoing automatic reset. Processing has stopped.

8.2 Status Indicator Bar

The status of all the critical operating modules is indicated in the “Status Bar” located across the bottom of the Main Menu screen.

<table>
<tr><td rowspan="2">Operating Status</td><td>Reagent Levels</td><td>Incubation Rail °C</td><td colspan="2">Lamp Status</td><td>Cuvette Boxes</td><td>Fresh Water</td><td colspan="2">Current Test Group</td><td>QC Status</td></tr>
<tr><td>Reagent Tray °C</td><td>Probe °C</td><td>Optical Meas. °C</td><td>Mech. Meas. °C</td><td>Cuvette Waste</td><td>Waste Water</td><td>Number of files in Archive</td><td>File format date</td><td>LIS Status</td></tr>
</table>

8.2.1 Operating Status

The left-hand side of the status bar at the bottom of the Main Menu screen displays the operating status. It provides information as to whether the instrument is ready to operate, is busy, or is waiting for an incubation to end. A black "Ready" is displayed when no error conditions exist and the instrument is available to begin processing. A red "Ready" indicates an error condition that needs operator attention before beginning processing. During processing, the area will be green when there are no error conditions on the sample currently being processed. The area will be red when an error condition on the sample has occurred (i.e., duplicate, no sample, timeout exceeded). The area will revert to green when measuring on the next sample begins. When "Wait" is displayed, a sample is incubating prior to measurement and no other tasks are imminent.

8.2.2 Reagent Level Monitor

Red with flashing “Chk. Reagent” when reagent is below the programmed minimum volume level. Area is empty when reagent levels are OK or have not been checked.

8.2.3 Temperature Monitors

The temperatures of five critical areas are constantly monitored. These areas are (1) Sample/Reagent area; (2) Incubation Rail; (3) Probe; (4) Optical Measuring Wells; and, (5) Mechanical Measuring Wells. The temperature area will be red with flashing numbers if the indicated temperature is outside of set limits. When temperatures are within the set limits, the numbers are displayed in black.

8.2.4 Lamp Monitor

The lamp status monitor indicates whether the lamp is ON or OFF. It will be a red "Wait" until the operational voltage output is reached. It will be a red field with flashing "Lamp error" if the lamp is burned out or otherwise inoperable. The area will be blank if all optical wells have been locked out.

8.2.5 Cuvette Box Monitor

A minimum of two cuvette boxes must always be present. When at least two boxes are in the cuvette chute, the field will display black "OK". The field will be red with flashing "Cups" if fewer than two boxes are present.

8.2.6 Cuvette Tray Waste Monitor

The cuvette boxes fall to the bottom of the chute area and are either removed from the chute manually or allowed to fall through a disposal opening into a waste container. When there are no more than two empty boxes in the chute area in front of the disposal opening, the monitor area will display as black "OK". When there are more than two boxes in the disposal area, the area will display as red with flashing yellow "Tray waste".

8.2.7 Fresh Water Input Monitor

When the input supply water level is adequate, the area will display as black "OK". When input water is below sensor level, the area will display as red with flashing "Empty".

8.2.8 Waste Water Output Monitor

When waste water in the output water container is below sensor level, the area will display as black "OK". When the waste water is above the sensor level, the area will display as red with flashing "Full".

8.2.9 Test Group Selection

Displays the currently selected test group. If no group is currently selected, the area is blank.

8.2.10 Number of Files in Archive

Displays the number of files stored in the patient archive since the last file format.

8.2.11 File Format Date

Displays the date the patient archive was formatted.

8.2.12 QC Status Monitor

When QC evaluation rules are enabled, the results of samples identified as QC material are monitored as the results are completed. When no rule violation has occurred, the area will display black “QcOK”. When a rule has been violated, the area displays as red with flashing “QcErr”.

8.2.13 LIS Status Monitor

Displays the status of the current transmission to the host interface.

Display	Description
Lis – black on white	Last transmission successful; all OK
Lis – black on red	Error in last transmission
Exp – yellow flashing on white	Data is being transmitted to host
Exp – yellow flashing on red	Data is being transmitted after previous error
Imp – yellow flashing on white	Data is being received from host
Imp – yellow flashing on red	Data is being received after a previous error

9 OPERATION - QUICK-START 9-1
9.1 ENTRY INTO QUICK-START 9-1
9.2 INTRODUCTION TO QUICK-START DIALOG WINDOW 9-3
9.3 TEST GROUP SELECTION 9-3
9.4 ORDERING TESTS 9-4
9.5 REAGENT TRAY PREPARATION 9-6
9.6 PRELIMINARY CHECKS 9-8
9.7 START PROCESSING 9-9
9.8 STOPPING OR ABORTING PROCESSING 9-10
9.9 VIEWING RESULTS 9-11
9.10 ADDING NEW SAMPLES 9-11
9.11 REPLENISHING REAGENTS 9-13
9.12 REPEATING TESTS 9-13
9.13 ADDING STAT SAMPLES 9-14
9.13.1 Stat Sample Deletion 9-15
9.14 PRINTING RESULTS 9-16
9.14.1 Routine Samples 9-17
9.14.2 Stat Samples 9-17
9.15 STARTING A NEW SAMPLE TRAY 9-18
9.16 CHECKING QC RESULTS 9-18
9.17 OPERATION AND MONITOR FUNCTIONS 9-18
9.17.1 Reagent Overview 9-19
9.17.2 AMAX 200 - Status 9-19
9.17.3 Prime 9-20
9.17.4 Wash 9-20
9.17.5 Test Groups 9-20
9.17.6 Check Reagent 9-20
9.17.7 Stop 9-20
9.17.8 Abort 9-20
9.18 EXITING QUICK-START 9-20
ABBREVIATED QUICK-START OPERATING PROCEDURE 9-22

The following are prerequisites to operation in the Quick-Start mode:

- System is powered up (Section 7).
- All operating parameters have been defined (Sections 18 and 19).

A Quick-Start summary is provided at the end of this section.

9.1 Entry into Quick-Start

"Quick-Start" is an alternative operation mode that has been designed to minimize operator interaction with multiple screens. Because it is so easy to use this operation mode, operators with minimal training may utilize it very effectively. It is also very useful in laboratories with continuous sample arrival.

In order to make operation of the AMAX 200 as simple as possible, the number of commands needed to operate have been reduced to an absolute minimum. All operations are carried out using a single dialog window.

Because a single dialog window is used, there are certain limitations when compared to the normal operating mode.

- All samples are identified by an ID code. Entry of full patient demographic information or location is not possible. Either a unique number or name may be used as the ID code.
- The integral barcode reader is not used. The barcode number may be entered either manually with the keyboard or with an off-line barcode reader.
- The number of tests that may be requested per sample is limited to 8.
- A maximum of 60 samples may be processed per processing period.
- The "Quick-Start" dialog window cannot be exited during processing.

Whenever the AMAX 200 is activated, the main menu screen appears:

<table>
<tr><td>Overview</td><td>Service</td><td>Measure</td><td colspan="2">Stat</td><td>Patients</td><td>System</td><td colspan="2">Q.C.</td><td>End</td></tr>
<tr><td colspan="10"></td></tr>
<tr><td rowspan="2">Operating Status</td><td>Reagent Levels</td><td>Incubation Rail °C</td><td colspan="2">Lamp Status</td><td>Cuvette Boxes</td><td>Fresh Water</td><td colspan="2">Current Test Group</td><td>QC Status</td></tr>
<tr><td>Reagent Tray °C</td><td>Probe °C</td><td>Optical Meas. °C</td><td>Mech. Meas. °C</td><td>Cuvette Waste</td><td>Waste Water</td><td>Number of files in Archive</td><td>File format date</td><td>LIS Status</td></tr>
</table>

The available menus are displayed across the top of the screen.

There are two ways to access the Quick-Start operating mode:

1. Using the **<arrow>** keys, move the cursor to **Stat** and press **<Enter>**; or,
2. Press **< t >**

   The "**Stat menu"** will open.

Overview	Service	Measure	Stat	Patients	System	Q.C.	End

				Quick-Start	If there are no Stat positions assigned in current Test Group reagent layout, only Quick-Start is displayed.				
				Quick-Start 1. Position 2. Position 3. Position 4. Position	If Stat positions are assigned in current Test Group Reagent Layout, the window also shows the number of assigned Stat positions (1-8).				
Operating Status	Reagent Levels	Incubation Rail °C	Lamp Status		Cuvette Boxes	Fresh Water	Current Test Group		QC Status
	Reagent Tray °C	Probe °C	Optical Meas. °C	Mech. Meas. °C	Cuvette Waste	Waste Water	Number of files in Archive	File format date	LIS Status

The Stat menu will open with the cursor on "Quick-Start".

With the cursor on Quick-Start, press **<Enter>**.

If a Test Group is active, the Quick-Start dialog window opens immediately. If no Test Group is currently selected, the "Select Test Group" dialog window appears. See Section 9.3, Step 3 for instructions on selecting a Test Group. If any reagents in the currently selected Test Group are expired, the "Expired reagent" dialog window will appear. Replace expired reagent(s) as necessary. After replacing reagents, respond to "Start run?" with **<y><Enter>**.

"/","*","-","+","R",<Space> selects, <Shift>-<Enter>, ↓,↑, copies
F1:Display F2:Print F3:Service F8:Panel F9:Process F10:Delete

P.	Identification	PT-O Sec	PTT-M Sec	FIB-O mg/dL	AT %A					
1										
2										
3										
4										
5										
6										

9.2 Introduction to Quick-Start Dialog Window

The keystrokes and function keys used to carry out tasks within Quick-Start are displayed in the two rows at the top of the screen. The listing serves as a reminder during operation. The use of these keys will be covered later when it's time to use them.

The numbers in the "P" column indicate the sample tray position number. The sample tray is numbered from 1 to 60. Samples are positioned consecutively in the tray. Up to sixty samples may be processed within any processing period.

The "Identification" column is used to identify the samples. Samples may be identified by either number or name (20-character limit). Anything that provides a unique entry is acceptable. The instrument will not accept duplication of any entered sequence. The entry must be unique.

The next 8 columns are used for test ordering. The short name codes listed at the top of each column are the tests that are available and may be ordered during the processing period. All processing on the AMAX 200 is done in "Test Groups". A Test Group in Quick-Start may be composed of any 8 currently programmed tests. The tests listed at the top of the column are those of the currently active test group.

9.3 Test Group Selection

The first consideration is to assure that the tests you want to run are available. Since all testing on the AMAX 200 is done by Test Groups, the first task is to pick a Test Group that contains the tests you want to run. In Quick-Start, a Test Group may be comprised of from 1 to 8 currently programmed tests. Test Groups cannot be defined within Quick-Start. The Test Group selection must be from those previously defined.

The currently active Test Group is always displayed in the bottom right-hand corner of the Main Menu Screen and is visible even when the Quick-Start dialog window is open. The Test Group for any given processing period may be selected from within Quick-Start.

19.1

The **<Function Keys>** at the top of the screen are used to perform certain tasks.

To select a Test Group:

1. Press **<F3>** (Service).
2. The Quick-Start Service submenu will open.

```
Reagent overview
CS200 - Status
Prime
Wash
Test Groups
Check Reagent
Stop
Abort
```

The Service submenu offers a variety of utility operations and monitoring functions. The complete use of this submenu is covered later.

3. Move the cursor to **<Test groups>** and confirm selection with **<Enter>**.

   The "Test Groups" selection window opens.

```
Group
Routine
PT
PTT
PT/PTT
Quick-Start
FIB
TT
Infac
Exfac
```

The window displays the code name for all defined test groups. The designation may be anything that adequately describes the test group. Test groups are not defined within Quick-Start.

It is common to have a "Quick-Start" test group defined that contains all tests (up to 8) that are routinely run in the Quick-Start operation mode.

It is useful to have a listing of the tests included in each test group posted near the instrument.

4. Move the cursor to the desired **<Test Group>** and confirm with **<Enter>**.
5. Press **<Esc>** to return to the Quick-Start dialog window.
6. The tests included in the selected test group are displayed at the top of the test ordering columns. Any one or all of these displayed tests may be run in the current processing sequence. If a test group is selected that contains more than 8 tests, only the first 8 tests in that group will be available.

9.4 Ordering Tests

1. **Patient samples**: Type a **unique** sample identification in the "Identification" column. Type in the appropriate numbers or characters. Press **<Enter**>. An off-line barcode reader (optional equipment) may be used to enter the ID. If the number or name entered is not unique, there will be an audible beep and a message that says "multiple!!!" is displayed. It means that this sample ID is already in the patient archive and cannot be used again in this file-formatting period.

QC samples are entered using a QC code which represents the ID Code defined for that control in combination with a 2-digit identifier sequence code. The 2-digit sequence identifier may be any combination of the following:

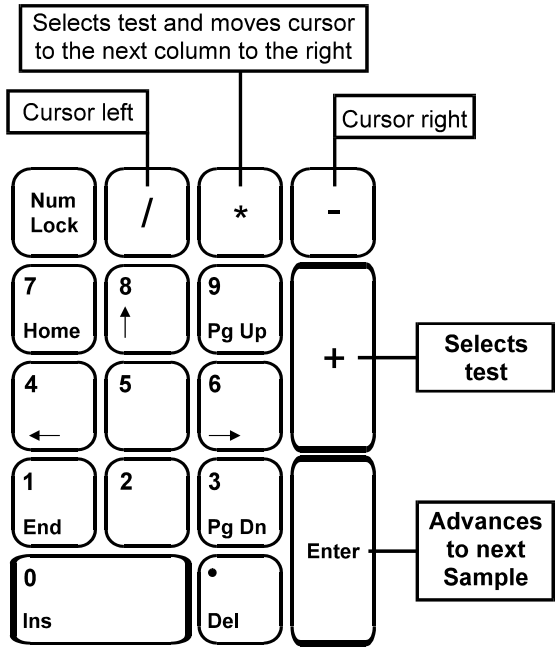
A. 00 through 99
B. A0 through Z9
C. 0A through 9Z
D. AA through ZZ

The 2-digit sequence identifier is prefaced by the ID Code defined for that specific control. For example: One of the defined controls is ACCUCLOT™ Normal and its ID Code has been defined as ACN. Valid ID entries to signal the AMAX 200 that this is a QC sample are: ACN00 through ACN99; ACNA0 through ACNZ9; ACN0A through ACN9Z; and, ACNAA through ACNZZ.

The same QC number cannot be used repeatedly. For example, the first AccuClot Normal after file formatting is called ACN00; the second ACN01; the third ACN02. If the QC code entered is not unique, there will be an audible beep and a message that says "multiple!!!" is displayed. It means that this QC ID code is already in the data archive and cannot be used again in this file-formatting period.

2. The cursor will move into the test ordering area.
3. The **<arrow>** keys are one way to move from place to place. Another, and usually more efficient way, is to use the numerical keypad. The numerical keypad is used to facilitate rapid test selection and movement through the dialog window.

   Order test(s) on the first sample as described below.



The **<Num Lock>** indicator light must be illuminated.

< / > moves the cursor one column to the left.

< – > moves the cursor one column to the right.

< * > orders the test assigned to that column and advances the cursor to the next column to the right.

< + > Orders test assigned to column.

<F8> (Function Key). Brings up a listing of defined panels. Type in the **<Panel #><Enter>**.

4. When a test is ordered, ***** fills the selected test column for that sample. If a test is ordered accidentally or if you change your mind and want to delete an already ordered test, the <Space> key on the letter keyboard deletes an ordered test. Move the cursor over the test you wish to remove and press the **<Space>** key.
5. New entries are displayed in yellow.

6. Once tests have been ordered on a sample, there are several options for proceeding. Which option to use is dependent on the next sample.

<Enter>	(either on character keyboard or on numeric keypad) advances the cursor to the next sample identification position and numerically increments the previous ID by 1.
<↓>	advances cursor to the next sample position without numerical increment ready for entry of the next sample ID.
<Shift-Enter> or **<Shift- ↓ >**	copies the ordered tests on the current sample to the next sample. If the sample has not been identified and a numeric ID was used for the previous sample, the next consecutive number will be automatically assigned as the ID-code.

7. Continue as above until the appropriate identification and tests have been completed for other samples that are ready for processing. More information on processing options is presented below. Note that if Quick-Start is exited prior to starting processing, all previously entered new IDs and test requests will be cancelled.

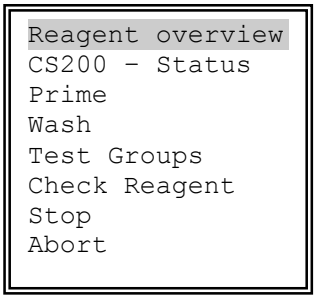
9.5 Reagent Tray Preparation

1. Each Test Group has an assigned Reagent Layout. A Reagent Layout designates the position of each reagent used by all the tests within the test group. The levels for all reagents used by the group are automatically checked prior to beginning processing.

   Reagent Layouts cannot be defined or modified from within Quick-Start.

19.3

   To find out what reagents are required, access the Service submenu by pressing **<F3>**.



   The submenu will open with the cursor on “Reagent overview”.

   Confirm the selection by pressing **<Enter>**.

   If for any reason the cursor is not on “Reagent overview”, use the **<↑>** or **<↓>** keys to position it correctly. Confirm with **<Enter>**.

   The “Reagent overview” window will open.

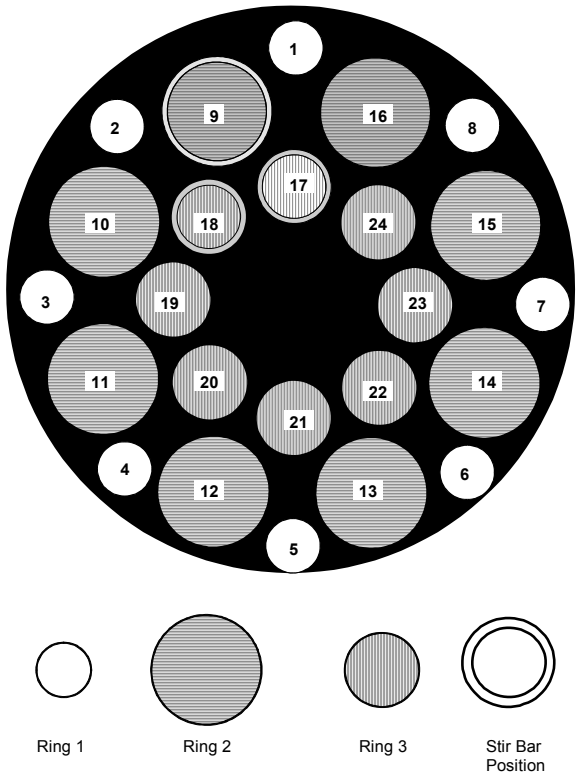
[Reagent overview]

	Cleaner		
	1. Ring (outer)	2. Ring (middle)	3. Ring (inner)
1	Stat	9 ThromboMAX	17
2	Stat	10	18 APTT
3	Stat	11	19 Calcium Chloride
4	Stat	12	20
5		13	21 Thrombin (FIB)
6		14	22
7		15 Imidazole Buffer	23 AT Thrombin/Hep
8		16	24 AT Substrate

The exact position in the reagent tray of all reagents required is displayed. The position number corresponds to a numbered position in the Reagent Tray.

The green bar indicates the last measured amount of each reagent. The red bar indicates the amount of reagent that has been used. If the red bar is flashing, the reagent is below the minimum level required prior to processing.

If the test group has been changed or if no processing has been performed using this reagent layout, all levels will be indicated in red regardless of the actual amount of reagent present.



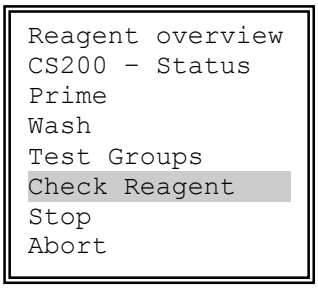
Although not required prior to processing, the reagent level monitor may be updated whenever the instrument is not processing. If levels are not monitored prior to processing, it is the responsibility of the Operator to assure that sufficient quantities of reagent(s) are present. If a new test group is selected or if this is the first processing period for the test group, when processing is started, the first task that the instrument performs is a check of the reagent levels. If the level of any reagent is below the minimum amount required prior to starting processing, no tests using that reagent will be processed. Tests with missing reagents will no longer be displayed at the top of the test ordering columns. If the cleaner is below the minimum required level, no tests will be processed.

2. Reagent levels may be checked either manually or automatically.

   To **manually** check levels: Remove the Plexiglas cover over the reagent tray storage area. Remove any lids present on all reagents assigned in the reagent layout. Check the reagent levels by examining each reagent container for an adequate fill.

Replenish reagent(s) as necessary. Reagent containers are considered disposable although they may be reused several times with appropriate periodic cleaning. Be sure to retrieve any stir bars prior to disposal. Replace cover when finished. The notch in the cover must be aligned with the matching alignment guide. There is a magnet on the lid that when in contact with the sensor on the lip of the storage area will assure that the cover is in the correct position.

To **automatically** check levels: If still in the Reagent Overview window, press **<Esc>** to close the window. The underlying Service submenu will be revealed. If performing this task from the Quick-Start dialog window, press **<F3>** to gain access to the Service submenu.



Assure that the lids have been removed from all assigned reagents. Reposition cover. The cover must be on and properly positioned.

Move the cursor to “Check reagent”. Confirm selection by pressing **<Enter>**.

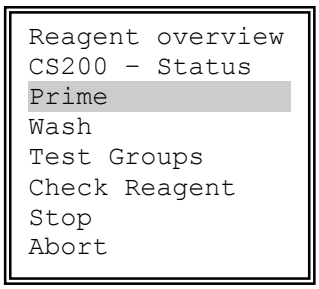
The robot probe will go to each assigned reagent position, check the level and update the monitor. The cleaner level is checked first and if the cleaner level is insufficient, no other levels will be checked. Return to the “Reagent Overview” window to observe the level check.

Replenish reagents as necessary.

9.6 Preliminary Checks

1. Check that the supply of fresh degassed water is adequate and that the waste container is not full. Replenish or empty as necessary.

   Optimum performance of the instrument is dependent on having a bubble free hydraulic system. If this is the first processing period of the day or if fresh degassed water has just been added, access the “Service” menu by pressing **<F3>**.



   Position the cursor over **“Prime”** and press **<Enter>**. Water will be primed through the system ensuring bubble-free operation. Observe the tubing entering and exiting the syringe. The persistence of a few small bubbles is not a cause for alarm but suggests that syringe maintenance may need to be done.

The priming process may also include a cleaning cycle if considered necessary. Position the cursor over **"Wash"** and press **<Enter>**. Water and cleaner will be pumped through the system. Sometimes the instrument will ask how many wash cycles you want to be done. Three (3) cycles are usually sufficient. Type **<3>** followed by **<Enter>**.

2. Assure that a minimum of two (2) cuvette boxes is available. The cuvette box loading chute will hold four boxes. A fifth box may be started into the chute. It will feed in as the first box is discarded.

   Insert cuvette box into the chute with the box oriented arrow side up with the arrows pointing into the chute.

3. Assure that lids have been removed from all reagents.

9.7 Start Processing

Press **<F9>** to start processing. The "Place new samples" window will be displayed.

1:	QC204	21:	41:
2:	301	22:	42:
3:	302	23:	43:
4:	303	24:	44:
5:	304	25:	45:
6:	305	26:	46:
7:	306	27:	47:
8:	307	28:	48:
9:	308	29:	49:
10:	309	30:	50:
11:	310	31:	51:
12:	QC104	32:	52:
13:	311	33:	53:
14:	312	34:	54:
15:	313	35:	55:
16:	314	36:	56:
17:	315	37:	57:
18:		38:	58:
19:		39:	59:
20:		40:	60:

The samples to be added are highlighted in red. The sample ID is directly opposite the sample's correct position in the sample tray. Remove cover and place each sample into its designated position. Reposition cover when finished. Processing will not start if the cover is off.

Press **<Enter>** when samples have been added and you are ready to begin processing.

If a new Test Group was selected or if this is the first processing period for the Test Group, reagent levels for all reagents in the reagent layout are checked. Sampling begins with the first unprocessed sample in the tray. The test processing order is

determined by the instrument. Processing order is prioritized according to the testing time. Shortest tests are processed first.

Prior to starting processing, ordered tests are indicated by **“ ***** “**. As soon as processing starts, the ordered tests display changes to **“. . . . .”**.

Note that if Quick-Start is exited prior to starting processing, all IDs and test requests will be cancelled.

9.8 Stopping or Aborting Processing

In the typical laboratory, things occasionally happen that require that processing be discontinued. Whether because of an emergency or simply because you forgot something, processing may be discontinued at anytime.

Processing does not have to be discontinued in order to add new samples (See 9.10, Adding New Samples).

Processing does not have to be discontinued in order to replenish reagents (See 9.11, Replenishing Reagents).

If at any time the instrument detects an emergency which might cause damage to the instrument if processing is continued, the instrument will immediately abort processing. For some critical situations, the AMAX 200 must be powered down. A message is displayed on the screen telling you what to do. Flip the ON/OFF switch to the OFF position. The green light will go out. Turn the PC OFF.

WARNING!
Do not switch OFF and ON rapidly. Wait 10-15 seconds after switching OFF before switching ON.

After 10-15 seconds, press the ON/OFF switch on the AMAX 200 to the ON position. Turn the PC back ON. Re-enter the Quick-Start dialog window after the Main Menu is displayed. See 9.1 above.

There are two operator-initiated ways to discontinue processing:

1. **Stop.** Stops the current processing. Sampling is discontinued but tests already sampled and currently in progress will be completed (soft stop).
2. **Abort.** Aborts the current processing. All tests currently in process are lost (hard stop).

   With software versions 3.1.13 and above, as soon as **<Abort>** is pressed, the “Abort confirmation” screen will be displayed:

   ```
   Confirm: NO
   ```

   If you do want to stop all processing, press **<y><Enter>**. If you do not want to lose all testing currently in progress, press **<Enter>** to deny the abort request.

   After appropriate corrective actions have been taken, restart processing by pressing **<F9>**.

9.9 Viewing Results

As soon as results are available, the test result is displayed in the appropriate test column. If an error condition occurs, it will be indicated in the test column.

You can always tell at a glance the status of any sample:

*****	tests ordered but not processed
. . . . .	tests ordered and are being processed, results not yet available
Numbers	testing completed
CV	duplicate error, %CV between duplicates not acceptable
NC	testing completed but no clot detected
empty	no reagent present
E	no sample present

For any test that has a calculated result, the display may be switched between the calculated result and the measured value (time or mE).

Press **<F1>** to open the result display dialog window.

Sec/mE = measured time or mE units (absorbance units)
Result = calculated result
Graphic = graphic display of optical reactions
Q.C. Charts = access to QC charts and QC data

Note that the "Result" displayed is the first calculated result defined in the "Data reduction" section of the test parameters. A calculated result may only be displayed if "C" or "R" is listed as the first reporting option in "Data reduction". If two calculated results are defined (e.g., Ratio and INR), only the first listed in "Data reduction" is displayed.

Move the cursor to the desired display and select with **<Enter>**.

If "**Graphic**" is selected, the Graphic Display screen is displayed. To activate graphics press **<F1>**. As optical reactions are taking place, the reaction progress will be displayed on the screen. The graphic reaction representation will also be stored in the patient file and may be retrieved later. Because throughput is slowed and because of the considerable amount of disc space that graphic storage requires, this option should not be used routinely. Pressing **<F6>** deactivates graphics. Graphics are printed by pressing **<F9>**.

Press **<Esc>** to return to the Quick-Start screen. The graphics option is covered extensively in later sections of this manual and only cursory coverage is given in this section.

15.5

If "**Q.C. Charts**" is selected, the thumbnail view of the active QC files is displayed. QC results may be accessed, reviewed and edited at any time during processing. More information is provided later in this chapter and in the "Quality Control Menu" chapter.

9.16
20.3.1
20.3.2

9.10 Adding New Samples

New samples may be added at almost any time during a processing period.

1. Using the < ↓ > key, move the cursor to the end of the patient list.

2. Type a unique Sample ID into the ID column. Complete with **<Enter>**.
3. Order tests as appropriate. The procedure is the same as that used in section 9.4. The acceptable keystrokes are displayed at the top of the screen.
4. Ordered tests will be indicated by *****. New patients will be displayed in yellow.
5. Press **<F9>** to start processing.

Processing is paused to allow positioning of the new sample(s). The screens that appear are dependent on what the instrument is doing when <F9> is pressed.

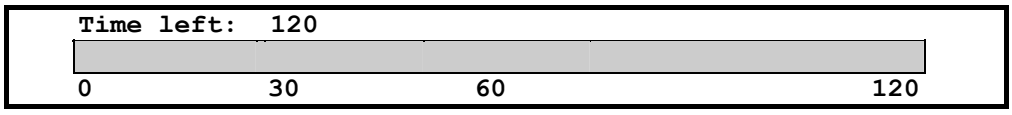
There will be occasions when there isn't enough time for the instrument to interupt processing before it has to do something else. In that event, the message “Run cannot be paused!” will appear on the screen.

```
Run cannot be paused!
```

After a short time delay, the “Please Wait” screen will replace this screen.

```
Please wait . . .
```

When processing may be paused, a time bar screen is displayed. This is a limited time procedure. The time you have to complete the addition is indicated on the screen.



Make a mental note of the time remaining and press **<any key>** to continue. “New samples added?” “YES” will appear on the screen. If the time allowed is sufficient, press **<Enter>** to continue. The “Place new samples” screen is displayed showing the sample tray position of the new samples. The robot goes to the far right. Position samples as indicated. If the time allotted is not sufficient, press **<n><Enter>**. Try again after the instrument has completed its current task. If time allows, reagent(s) may also be replenished at this time.

When the new samples have been placed into the sample tray, press **<Enter>** to start processing.

Whether or not new samples will be processed during the current processing period depends on the stage of processing the instrument is in. Each Test Group has a defined batch size that determines the number of samples included in a batch. For example: If the batch size is 4, all tests on 4 samples will be processed before going to the next group of 4 samples. If processing has begun on the sample group in which the new sample would normally be a member, processing will not be done in this processing period.

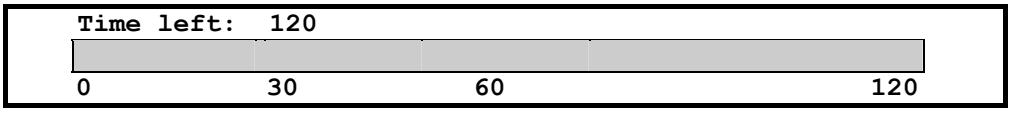
If a sample has been included in the current processing period, the ***** display will change to **.....** The display color will change from yellow (new) to blue (old or in process).

If new samples are not included in the current processing period, they may be processed by pressing **<F9>** as soon as the current processing period is completed.

9.11 Replenishing Reagents

Reagents may be replenished at almost any time during a processing period. The procedure used is the same as when adding new samples. <F9> is used to pause processing.

1. Reconstitute or otherwise prepare reagent for use. Reagent must be ready to add as soon as the pause procedure is initiated.
2. Press **<F9>** to pause processing. The "Run cannot be paused!" and "Please wait …" screens may be displayed. When processing may be paused, a time bar screen is displayed. The time you have to complete the addition is indicated on the screen.



3. If the time allowed is sufficient, press **<Enter>** to continue. The instrument thinks you are going to add new samples and will display the "Place new samples" screen. The robot goes to the far right. Ignore the request to position new samples. If the time allotted is not sufficient to complete reagent replenishment, press **<n><Enter>**. Try again after the instrument has completed its tasks.
4. Remove the cover to the Sample/Reagent Trays area. Replenish reagents as necessary.
5. When reagent has been replenished, replace cover and press **<Enter>** to re-start processing.

9.12 Repeating Tests

Any or all tests may be repeated at the discretion of the operator. Tests resulting in an error condition should always be repeated. Tests ending in an unexpected result should always be repeated. Repetition of abnormal test results is at the discretion of the Operator.

The request for test repeat may be done at any time after the sample has been processed and results are indicated on the screen. Note that if the test repeat request is made while the instrument is not currently processing and Quick-Start is exited prior to re-starting processing, the repeat request will be cancelled. Upon re-entry into Quick-Start, the original results will be displayed.

Position the cursor over the specific test result on a particular sample that is to be repeated. Press **<r>**. The repeat request screen will appear.

Confirm that the test is to be repeated by pressing **<y>** followed by **<Enter>**. If you decide not to repeat the test, press **<Enter>**. Once repeat testing has been requested, the previous result is no longer available.

Since processing has already been completed on this test, repeat testing will not be included in the current processing period. The previously displayed result or error condition will be replaced by " ***** " indicating that the test has been reordered.

Any error condition must be corrected prior to starting processing.

At the end of the current processing period, press **<F9>** to restart processing. A screen showing the samples to be processed will appear on the screen. Assure that all the indicated samples are present in the designated position of the sample tray and that there is sufficient sample present for the tests to be processed. Assure that a sufficient supply of reagent is present.

After all prerequisite conditions have been fulfilled, press **<Enter>** to confirm the start of processing.

" ***** " will change to " ..... " indicating that processing has begun.

9.13 Adding Stat Samples

Stat samples are positioned in the reagent tray not the sample tray. **Stat samples may be processed in Quick-Start only if the reagent layout for the test group is defined to include Stat samples and if the required reagents are present at the start of processing.** Reagent layouts cannot be defined or modified from within Quick-Start.

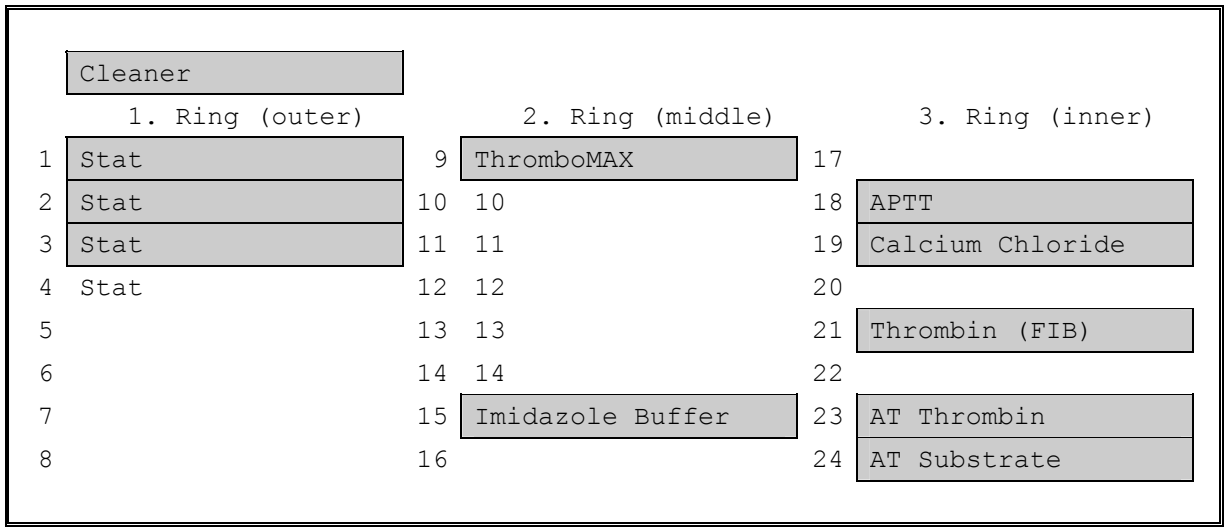
19.3.1.c

In the Quick-Start dialog window, the Stat sample positions are above the normal sample entry positions. To check to see if Stat positions are available, use the < ↑ > to move the cursor to sample position 1. Press the < ↑ > again. If Stat positions are available, the cursor will move into the Stat ordering area. **If no Stat positions are defined, entry into the Stat request area will be denied.**

P.	Identification	PT-O Sec	PTT-M Sec	FIB-O mg/dL	AT %A					
S1	1210	*****	*****							
S2										
S3										
S4										
1	QC204	22.5	49.6							
2	301	18.1	.....							
3	302	14.3	.....	.....						
4	303	.....	.....							
5	304	.....	.....							

Another way to check to see if Stat positions are available is to press **<F3>** to display the Service menu. With the cursor over "Reagent overview", press **<Enter>**.

[Reagent overview]



Positions 1 through 8 in any given reagent layout may be used for either reagents or as Stat sample positions. These positions must be predefined. It is not possible to define or modify reagent layouts in Quick-Start.

19.3.1.C

Stat positions that have already been used are highlighted in red.

Press **<Esc>** to return to the Quick-Start dialog window.

Go to the first available Stat position and make the appropriate ID and test request entries in the same way as for “normal” samples (see 9.4).

When request information has been completed, press **<F9>** to start processing. Processing is temporarily paused to allow sample positioning. Respond to the “CS200 Pause” windows as described in Section 9.10, Adding New Samples. Position samples in their programmed Stat position. Replace cover and press **<Enter>**.

Note that the volume of sample in the tube must be of sufficient amount so that the top of the liquid is above the bottom level set for sample in the normal 1-60 positions. This is particularly critical for the Sample Trays where 12x75 mm tubes either sit on the middle shelf of the Sample Tray or for the Sample Trays fitted with O-rings that may be used with multiple tube sizes. The bottom of the Reagent Tray is level with the bottom shelf of the Sample Tray. To minimize the amount of sample needed in the Stat positions, do not seat the tube to the bottom of the Reagent Tray. Position tube bottom closer to the middle shelf which is the same height as the middle shelf of the Sample Tray.

When processing on the Stat(s) has begun, “ ***** “ will be replaced by “ ..... “.

9.13.1 Stat Sample Deletion

If for any reason you decide not to run the sample as a Stat, a single Stat sample may be deleted prior to the initiation of processing. Once the sample information has been transferred to the patient archive, the sample may be run normally.

Once a Stat position has been used, it cannot be reused until the Stat sample is transferred out of the Stat files and into the patient archive files. A Stat is transferred using the “Delete” function.

No information is lost when a Stat sample is deleted. The "deletion" process transfers all ID and test information into the patient archive. With the cursor over the Stat sample that you wish to delete, press **<F10>**. Only that sample will be deleted. Only single Stat samples may be deleted in this manner. Samples loaded in "normal" positions cannot be deleted singly. When the cursor is in the "normal" area of the Quick-Start screen, all samples are deleted by pressing <F10>. More information is given in section 9.15.

A Stat sample cannot be deleted while it is processing. Once processing has been completed, the Stat position may be deleted to open the position to accommodate an additional Stat sample. No information is lost when a Stat sample is deleted. The "deletion" process transfers all ID and test information into the patient archive. The Stat position is then available for reuse.

9.14 Printing Results

Results are printed out in real-time during processing. As soon as all requested tests that are being processed on a sample are completed, the results for all tests on that sample are printed. Real-time results do not necessarily printout in ID sequence, or in position sequence.

ATTENTION!
Real-time results do not necessarily printout in ID sequence.
Always check the ID prior to reporting any results.

A collated result list may be printed at any time. The result list contains all results on selected patients; or, if processing on selected samples is not completed, a status report on ordered tests is printed. An interim report on individually selected Stat samples may be printed.

Press **<F2>** to open the "Print" submenus. "Stat #" is only present if Stat positions are defined in the Reagent Layout for the selected Test Group.

Results
Stat 1
Stat 2
Stat 3
Stat 4

Selecting "Results" provides printing access to results in the patient archive.

Selecting one of the "Stat #" provides a way to add a name and location to a Stat sample and to print interim results for the selected Stat position.

9.14.1 Routine Samples

With the cursor on “Results”, press <Enter>. The “Result list” dialog window will be displayed.

[Result list]

```
from:

to:

Confirm: NO
```

from: first sample ID to be included in printout
to: last sample ID to be included in printout

A. With the cursor at “from:” Type the sample ID for the first sample to be included in the printout. Complete with **<Enter>**.

ATTENTION!
Failure to make a valid entry into this field will result in printout of all results from the beginning of the patient archive up to the specified “to” ID.

B. The cursor advances to “to:”. Type the sample ID for the last sample to be included in the printout. Complete with **<Enter>**.

ATTENTION!
Failure to make a valid entry into this field will result in printout of all results from the specified “from” ID to the end of the patient archive.

C. The cursor advances to “Confirm: NO”. If everything is acceptable (pay particular attention to the entries for “from:” and “to:”), confirm by pressing **<y>** followed by **<Enter>**.

Printout of the collated results on the inclusive sample ID's commences.

Press **<Esc>** to return to the Quick-Start dialog window.

9.14.2 Stat Samples

With the “Print submenu” open, move the cursor to the “Stat #” of the sample to be printed, press **<Enter>**. The “Stat #” dialog window will be displayed.

[Stat 1]

```
Ident.:S052899-14
Name  :Harry Houdini
Loc.  :ICU
   -------TESTS-------
   FIB             85
   PT              Pending
   PTT
```

The ID number assigned in the corresponding Stat position of the Quick-Start screen will have been transferred into the “Ident.” position.

The sample may be further identified as appropriate with the addition of a name and location.

The test codes listed below "TESTS" will be those that are available in the currently selected Test Group. A result will be displayed for any tests that have been ordered and completed. If the test has been ordered but is not yet completed, the message assigned to Error Code 0 (Not Processed code) will be displayed.

A formal report cannot be printed on any Stat sample until the Stat sample has been transferred into the patient archive. An interim report may be printed by pressing **<Print Screen>**. The "Stat #" dialog window will be printed.

9.15 Starting a New Sample Tray

Starting over with a new sample tray may be done anytime the instrument is not currently processing samples. Sample results are not lost and may be retrieved at any time using **<F2>** (print results). Sample IDs and test results will no longer be displayed on the Quick-Start dialog window. Nothing further may be processed in Quick-Start mode on these samples.

When all 60 sample positions in a sample tray have been used, the sample tray must be emptied to enable processing of a new sample tray. It may also be desirable to start anew if all the Stat positions have been used.

1. Press **<F10>**.
   A window will appear asking the question: "Cancel samples? NO".
2. Confirm your desire to delete the current sample tray by pressing **<y>** followed by **<Enter>**.

The Quick-Start dialog window will contain no entries. Sample addition begins at position 1. Previous samples must be removed from the sample tray.

9.16 Checking QC Results

QC results may be accessed, reviewed and edited at any time by pressing **<F1><Q.C. Charts>**.

The thumbnail charts for all active QC files will be displayed.

Use the page down key to move to the next page of charts and the page up key to go back to the previous page of charts. Detailed information for each chart may be accessed by using the page up, page down and arrow keys to move a specific chart and pressing **<Enter>**. Detailed information on QC editing may be found in Chapter 20.

20.3.1
20.3.2

9.17 Operation and Monitor Functions

Once familiar with the operation of the AMAX 200, there are certain operations that you may wish to perform or monitor. All of these operations are accessed through the "Service" menu. All except one of these operations have already been described in this section. For operations already described, this section will serve as a summary review.

Press **<F3>** to access the "Service" menu.

```
Reagent overview
AMAX200 - Status
Prime
Wash
Test groups
Check reagent
Stop
Abort
```

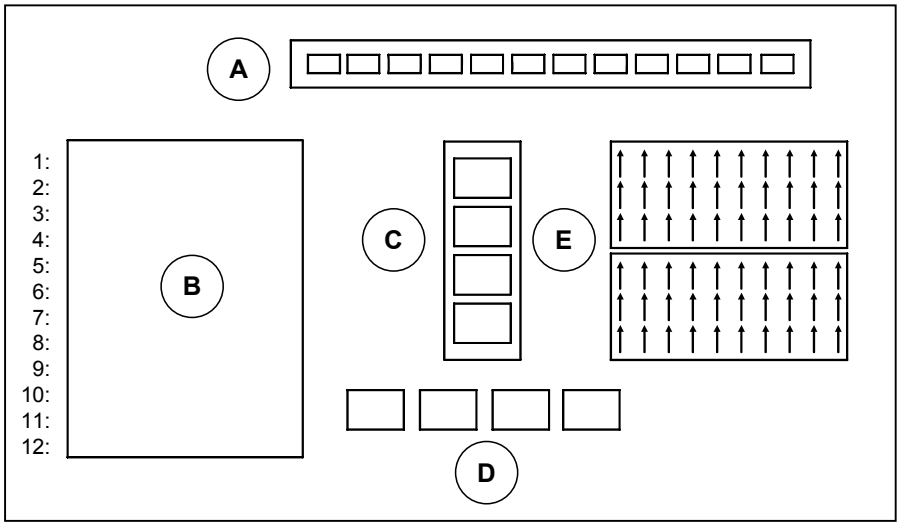
9.17.1 Reagent Overview

Shows the reagent layout in use. Shows exact position for each reagent and provides information on the levels of reagent present. The location, availability and status of any Stat positions are also shown.

9.17.2 AMAX 200 - Status

During processing you may want to see just what is going on with regards to incubation and measuring. The status may be viewed at any time by accessing the "CS200 - Status" window. This is a monitor-only operation. Nothing may be done except to look at what is happening.

Position the cursor over "**AMAX 200 - Status**" and press **<Enter>**. The "AMAX200 - Status" window appears.



Key	Description
A	12-position incubation rail area. Incubation area for samples in process prior to addition of starting reagent. RED = position contains a sample in process. GREEN = open incubation position.
B	Sample identification area. Contains a listing of the group/ batch of samples currently being processed. See Chapter 12, Section 12.4, DOS option "ITCHK" for an alternative display option.

Key	Description
C	Optical measuring wells. RED = measurement in process. Real-time graphic reaction representation may be obtained (graphics mode ON). GREEN = open measuring position. BLACK = position has been locked and will not be used for measurement.
D	Mechanical measuring wells. RED = measurement in process. GREEN = open measuring position. BLACK = position has been locked and will not be used for measurement.
E	Cuvette box area. GREEN = box present. RED = box missing. Run will be aborted if not replaced.

9.17.3 Prime

"Prime" is used to prime the system assuring a bubble-free hydraulic system.

9.17.4 Wash

"Wash" is used to prime and decontaminate the system.

9.17.5 Test Groups

"Test groups" is used to select a Test Group to be used during the current processing period.

9.17.6 Check Reagent

"Check reagent" is used to update the reagent level monitor prior to the start of processing.

9.17.7 Stop

"Stop" is used to interrupt processing. Sampling is stopped. Tests currently in progress are completed.

9.17.8 Abort

"Abort" is used to immediately terminate processing. Sampling is stopped. Tests currently in preparation or incubation are cancelled. Tests in the measuring wells are completed.

9.18 Exiting Quick-Start

Exiting the Quick-Start operation mode is not allowed during processing. Once processing has started, you cannot leave Quick-Start without stopping processing.

When new IDs or repeat requests have been entered, if Quick-Start is exited without starting processing, all newly entered IDs and repeat requests will be deleted.

Quick-Start may be exited and re-entered without losing any data after a processing period is completed. Any new IDs or repeat requests entered prior to processing stop will not be lost.

To exit the Quick-Start mode, press **<Esc>**. Note that pressing <Esc> during processing will not exit the mode. The **<Esc>** command will be ignored.

After pressing **<Esc>**, an exit confirmation window will open.

```
Leave Quick-Start?  NO
```

To confirm that you do indeed wish to leave Quick-Start, press **<y>** followed by **<Enter>**. The Main Menu screen will be displayed.

If you wish to remain in Quick-Start, respond to the “Leave Quick-Start? NO” message by pressing **<Enter>**. The Quick-Start dialog window will be displayed.

Abbreviated Quick-Start Operating Procedure:

		Chapter Reference
1.	Enter Quick-Start: **<Stat Menu><Enter><Quick-Start><Enter>**	**9.1**
2.	Test Group Selection: **<F3><Test groups><Enter><Appropriate Group><Enter>**	**9.3**
3.	Order Tests: **<Type ID><Enter>** and **< → >** to go to **<test to be ordered>** select with **< ✷ > or <+>**. **<F8>** to go to panel list **<panel #><Enter>** to order all tests in the panel. **< / >** backs cursor to the left, **< - >** advances cursor to the right. **<Enter>** advances to the next sample ID. **<Shift-Enter>** or **<Shift ↓>** copies ordered same tests to next sample.	**9.4**
4.	Prepare Reagent Tray: **<F3><Reagent overview><Enter>** to see reagent layout. Check for sufficient amounts either manually or automatically. Remove all lids. Automatic: **<F3><Check reagent><Enter>**. Replenish reagents as necessary.	**9.5**
5.	Check fresh water supply and drain waste. Fill or empty as necessary. Check cuvette boxes supply. Add as necessary.	**9.6**
6.	Start Processing: Position samples appropriately. **<F9>** to start processing. Screen displays order of samples. **<Enter>** to confirm and start run.	**9.7**
7.	Stop Processing: **<F3><Stop><Enter>** for a soft stop; or **<Abort><Enter>** for a hard stop.	**9.8**
8.	Check QC results: **<F1><Q.C. Charts>**	**9.9**
9.	Add New Samples: Go to next open position. Type in ID and order tests. **<F9>** to start processing.	**9.10**
10.	Repeating Tests: With cursor over test to be repeated: **<r><y><Enter>**. At end of current processing period, press **<F9>** to start processing repeat samples.	**9.12**
11.	Adding Stats: Go to first sample. **< ↑ >** to Stat entry screen. Type in ID and order tests. **<F9>** to start processing.	**9.13**
12.	Printing Results: **<F2>** "From"/"to": **<starting sample ID><Enter><Ending sample ID><Enter>** Confirm: **<y><Enter>** starts printout.	**9.14**
13.	Starting Over: **<F10><y><Enter>** deletes sample tray.	**9.15**
14.	Exiting Quick-Start: When not processing: **<Esc><y><Enter>**.	**9.17**

10 OPERATION - NORMAL 10-1
10.1 REAGENT PREPARATION 10-1
10.2 FRESH AND WASTE WATER CHECKS 10-3
10.3 CUVETTE PREPARATION 10-4
10.4 FORMAT DATA FILES 10-6
10.5 SAMPLE IDENTIFICATION, POSITIONING AND TEST REQUISITIONING 10-6
10.5.1 Keyboard Addition of New Patients 10-8
10.5.2 Keyboard Edit of Old Patients 10-10
10.5.3 Position Samples in Sample Tray 10-11
10.6 START PROCESSING 10-11
10.6.1 Select Test Group 10-12
10.6.2 Start 10-12
10.7 PAUSE, STOP AND ABORT 10-15
10.7.1 Pause 10-15
10.7.2 Stop 10-16
10.7.3 Abort 10-16
10.8 STAT TESTING 10-16
10.8.1 Stat Requisitioning 10-16
10.8.2 Viewing and Printing Stat Results 10-17
10.8.3 Emptying Stat Positions and Transferring Sample to Archive 10-17
10.9 OVERVIEW 10-18
10.10 GRAPHIC MODE 10-18
10.11 REPEAT TESTING 10-18
10.12 PRINTOUT OF RESULTS 10-19
10.13 EVALUATION OF QC RESULTS 10-20
10.14 PRINTOUT OF PATIENT REPORTS 10-21
10.15 ERRORS DURING PROCESSING: NON-FATAL 10-21
10.16 ERRORS DURING PROCESSING: FATAL 10-22
10.17 SHUTDOWN 10-23

In the Normal Operating Mode, the operator interacts with multiple dialog windows that provide maximum utilization of all the features of the AMAX 200.

This section assumes that the following prerequisites to operation are already in place:

- System is powered up (Section 7); and,
- All operating parameters have been defined (Sections 18 and 19).

For additional information on topics covered extensively in other sections of this manual, go to the indicated reference section.

10.1 Reagent Preparation

1. All testing on the AMAX 200 is done in Test Groups. A Test Group is a defined group of from 1 to 12 tests. The currently active Test Group is always displayed in the lower right-hand corner of the Main Menu screen. If no group is selected, the area above the file format date will be blank.

19.1

   A Reagent Layout defines the exact location of a group of reagents. Most laboratories have multiple reagent layouts. It is recommended that when a reagent is assigned to more than one layout, the positioning be the same in all layouts. One Reagent Layout is assigned to every Test Group. Whenever the Test Group is active, the assigned Reagent Layout is active and the instrument expects to see all reagents assigned in that layout.

19.3

   If the currently active Test Group is not the one you want to use, select a different Test Group that includes the tests you want to run: **<Measure><Test Groups>.** Move the cursor to the **<desired group>** and press **<Enter>**.

19.1

2. To display the load map for the Reagent Layout assigned to the selected Test Group: **<Overview><Reagent>**

13.2

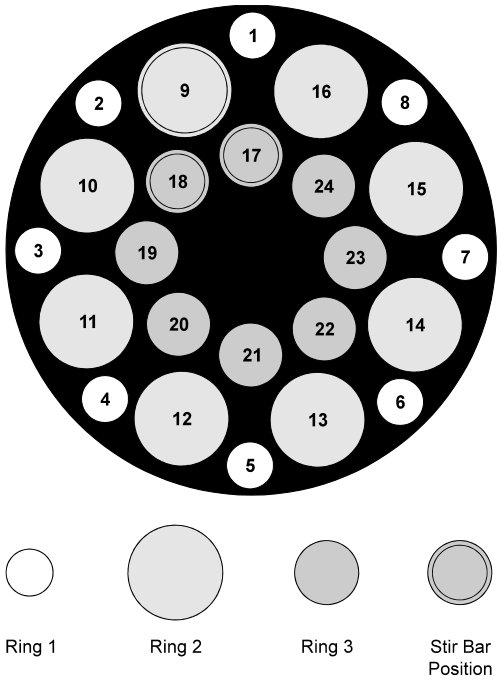
Cleaner

1. Ring (outer)	2. Ring (middle)	3. Ring (inner)
1 Stat	9 ThromboMAX	17
2 Stat	10	18 APTT
3 Stat	11	19 Calcium Chloride
4 Stat	12	20
5 Stat	13	21 Thrombin (FIB)
6 Stat	14	22
7 Stat	15 Imidazole Buffer	23 AT Heparin/Thrombin
8 Stat	16	24 AT Substrate

The exact position of every reagent assigned to the Reagent Layout is displayed. The position number corresponds to a numbered position in the Reagent Tray.

The green bar indicates the last measured level of each reagent. The red part of the bar indicates the amount of reagent that has been used. If a new Test Group is selected, all levels will be red regardless of the amount of reagent present.

The bar proportions are displayed according to the “Maximum volume” parameter in the Reagent Definition parameters.



3. Check that there is sufficient reagent for all testing to be performed. When Positive Id is active, all reagents must be present prior to processing start. Enzyclean is the system cleaner and must always be present.

14.4

Enzyclean is either poured into the trough next to the incubation rail; or, a 15-mL bottle of Enzyclean may be placed in the right-hand end of the trough. Reagent volume check may be performed either manually by examining each reagent container or automatically.

To **automatically** check the reagent levels:

A. Remove all lids.

B. Select <Service><Check reagent>.

C. The probe will go to each reagent position assigned in the layout and check the reagent level. Note that if the Enzyclean level is below the defined minimum volume, no other reagents will be checked.

D. The reagent usage monitor will be updated and may be viewed by returning to the Reagent Overview display window (<Overview><Reagent>).

4. Replenish reagents as necessary. Reconstitute reagents following the directions in the reagent manufacturer's application for the AMAX 200 .

ATTENTION!
The reactivity of expired reagents is unreliable. Do not use unreconstituted reagents beyond the listed expiration date. Do not use reconstituted reagents beyond established stability claim limits.

5. Place reagents into appropriately sized containers. The maximum reagent level in bottles with necks should be the lower edge of the neck. Level sensing may fail if the bottle is over-filled. Reagent usage monitoring will be most accurate and reliable if all reagent containers within a ring are the same size. The following containers are recommended:

Reagent ring 1	12x75 mm plastic tubes	
Reagent ring 2	20 mL glass, screw-cap	Catalog No. K 2508
Reagent ring 3	12 ml plastic vial, snap-cap	Catalog No. K 2758

ATTENTION!
Continued repeated addition of new reagent to old reagent may lead to changes in the reagent composition that may change its reactivity. It may also lead to microbial contamination, which will seriously compromise reagent stability. Reagent containers that are reused should be thoroughly decontaminated with 10% bleach, rinsed thoroughly in tap water, rinsed in DI water and dried prior to reuse.

To avoid contamination and the deleterious effects of evaporation, reagents should be capped when not in use. Calcium chloride is hygroscopic and is particularly prone to molarity changes if kept uncapped for extended periods.

6. A stir bar should be added to any reagent that is particulate. A special stir bar with wings (Catalogue No. A 6208) should be used for any kaolin-containing reagents. Reagent containers with stir bars must be placed in reagent tray position 9, 17 or 18.

ATTENTION!
Stir bars should be periodically decontaminated with 10% bleach, rinsed thoroughly with tap water, and rinsed with DI water.

7. Remove storage area cover. Place reagents into their assigned positions in the Reagent Tray. Place the Reagent Tray into the storage area taking care to align the hole in the bottom of the tray over the guide pin in the bottom of the storage area.
8. Replace storage area cover when finished. The cover must be on at the start of processing. To facilitate temperature regulation within the storage area, it is recommended that the cover be kept on except when actually working within the area.

10.2 Fresh and Waste Water Checks

1. Check the supply of fresh DI water. Replenish as necessary. If using water from a highly pressurized DI source, best performance is attained using degassed water. The easiest way to degas water is to let it sit for a minimum of 8-12 hours. It is convenient to have an extra 21 L container that may be filled ahead of time and be degassed by the time it is needed.

The container should be emptied and rinsed periodically. If contamination is suspected, decontaminate with 10% bleach. Rinse thoroughly with tap water. Rinse thoroughly with DI water. Let container dry before reuse.

2. Check that the waste container is not full. Empty as necessary.

WARNING!
Potentially biohazardous waste. Handle according to laboratory safety regulations.

Addition of a concentrated biohazardous waste disinfectant is recommended (such as Lysol® IC™ Brand Quaternary Disinfectant Cleaner or equivalent quaternary ammonium disinfectant). Add the amount of concentrated disinfectant recommended by the manufacturer to effect disinfection of biohazardous materials (e.g., a l:256 dilution of Lysol® IC™ is recommended by the manufacturer. When the waste container is full, it will contain approximately 19 L of waste fluid. 19000/256 = 74 mL. The addition of approximately 75 mL of concentrated Lysol® IC™ will effectively decontaminate the contents of a full waste container.)

Lysol® IC™ is a registered trademark of National Laboratories, L&F Products, Montvale, NJ 07645

Perform a system Prime or Wash. Optimum performance is dependent on having a bubble-free hydraulic system. Prime should always be performed after adding fresh water or anytime the suction/sensor assembly is removed from the fresh water container.

14.1
14.2

The lines leading to and from the syringe should be visually examined daily for bubbles and air gaps.

To prime the system: **<Service><Prime>** or **<Wash>**

Prime pumps only water through the system. A wash includes Enzyclean and cleans both probe and tubing. Observe the lines leading to and from the syringe. If bubbles are observed, flick the tubing during the priming process to move the bubbles into the syringe so that they will be pumped out through the probe.

ATTENTION!
Repeat if large bubbles or air gaps persist.

A few small bubbles are not a cause for alarm although their presence may suggest that the syringe needs to be cleaned or replaced

23.4.1
23.6.2

10.3 Cuvette Preparation

1. Assure that a minimum of two boxes of cuvettes are in the chute. The chute will hold 4 boxes. A fifth box may be started into the chute. It will feed in as the first box is discarded.

Insert cuvette box into the chute with the box oriented arrow side up with the arrows pointing into the chute.

ATTENTION!
Careful attention to the arrows on the top of the cuvette boxes is critical to trouble-free operation of the cuvette transfer mechanism. The boxes must be inserted with the arrows showing on the top and pointing into the chute.

2. To prepare a cuvette box for addition:
   A. Insert into the chute with the box oriented arrow side up with the arrows pointing into the chute.
   B. Push the box all the way in the chute until it touches the box in front of it, making sure that the box is properly aligned in the chute.
3. Assure that the cuvette and cuvette box disposal areas are not full. Cuvettes are discarded during processing through the bottom of the measuring wells. The discarded cuvettes fall into the drawer below the measuring area.

WARNING!
Potentially biohazardous waste. Handle according to laboratory safety regulations.

It is recommended that a biohazardous waste collection bag or liner be inserted into the cuvette disposal area.

Empty cuvette boxes are transported out of the back of the chute and fall into the disposal area below the chute. The cuvette boxes are manufactured using recyclable plastic and may be recycled according to laboratory recycling policies.

10.4 Format Data Files

A data file is prepared for each unique ID code. A data file includes demographic information and all associated test requisitions and results. A data file may belong to either a patient or a control material. All data files are temporarily stored in the "patient archive". In addition to being stored in the patient archive, QC results are also stored in the "QC archive". The patient archive may hold up to 1,020 data files. All patient archive data remains stored until it is deleted. It is customary to delete the previous day's data files prior to starting a new day. All data files in the patient archive are deleted using the "Format Data Files" function. No data is deleted from the QC archive during file formatting.

ATTENTION!
When the data file is formatted, all stored information is deleted. Make sure that there is no further need for this information before formatting the file.

To delete the data files in the patient archive:

<System><Format data file>

```
F O R M A T   P A T I E N T   F I L E
All contained data will be lost ! !
          Confirm :  NO
```

If all data has been evaluated and/or stored elsewhere, confirm the file deletion with **<y><Enter>**. Once formatting is completed, the lower right-hand corner of the Main Menu status bar will say "0 today", indicating that there are no files in the patient archive and that the file was formatted today.

If you decide not to go ahead with the file formatting, deny the deletion by pressing **<Enter>**.

10.5 Sample Identification, Positioning and Test Requisitioning

The AMAX 200 has an integral barcode reader that may be either active or inactive. Samples may be identified and positioned either by the use of barcodes or by keyboard entry. When the "Positive-Id" option is active, the barcode reader is active and identifies samples as it reads the barcode. Samples may be positioned anywhere in a tray. When the "Position oriented" option is active, the internal barcode reader is inactive and all samples are identified and positioned through the keyboard.

When "Positive Id" is active, there are two options for the way in which tests are requisitioned. Tests may either be requested individually on each sample; or, all tests comprising the Test Group may be requested on all samples. When the "Requests only" option is active, tests are requested as appropriate on each sample using either a download from a LIS or through the keyboard. Only the requested tests will be run. When the "Automatic profile" option is active, all tests in the Test Group will be run on all samples. "Automatic profile" is not available with the "Position oriented" option.

There are two choices to be made:

- Will sample identification and positioning be by barcode (“Positive Id” on); or by keyboard entry (“Position oriented” on)?
- If “Positive Id” is active, will test requisition be by “requests only” or “automatic profile”?

To select the appropriate options:
Password Security system: **<System><Password><Options><Enter>**
PIN Security system: **<System><Operator 1, 2 or 4 Sign On><Options><Enter>**

```
♦ Positive Id
  Position oriented
♦ Print protocol
  No protocol
  Extended protocol
♦ Reduced protocol
♦ On-Line: Real-Time
  On-Line: Batch
  Autom. Profile
♦ Requests only
```

18.5

Current selections are marked with ►.

These are all paired options.

- Sample identification may either be “Positive Id” (barcode) or “Position oriented” (keyboard).
- Real-time results may be either printed or not printed using “Print protocol” and “No protocol”.
- The real-time printout may either be in an “Extended protocol” or a “Reduced protocol”.
- Host computer requisitioning may either be “On-Line: Real-Time” or “On-Line: Batch”.
- Tests may be requisitioned either as an “Automatic Profile” or by “Requests only”.

Move the cursor to the option you want to activate and press **<Enter>**. The opposite pair member will automatically deselect (e.g., if “Positive Id” is selected, “Position oriented” will automatically deselect; if “Autom. Profile” is selected, “Requests only” will automatically deselect).

1. If “Positive Id” and “Automatic Profile” are active, nothing further needs to be done before starting processing except to place the barcoded samples in the Sample Tray. Samples may go into any position. The scanning always starts from position 1 and progresses around the tray. A full tray search may take up to 5 minutes. For a fast start-up, avoid placing unprocessed samples at the end of the tray.
2. If “Position oriented” is selected, all samples are assigned a tray position number. All identification, positioning and requisition entry is through the keyboard.

10.5.1 Keyboard Addition of New Patients

A. **<Patients><New>**: The "Enter new samples" dialog window opens.

17.1

F2:Advance F3:Tests F4:Store panel F5:Multiple samples F8:Panel

[Enter new samples]

```
Seq. number   :        1
Tray/Posit.   :        3/4
Ident.:  485467573
Name  :
Loc   :
Note  :
- - - - - - - TESTS - - - - - - -
PT PTT   FIB      AT
```

B. When the window opens, the cursor will be in the "Ident." field. The numbers in the "Tray/Posit." field are the first tray that has empty positions available and the first available empty position. This may or may not be the tray that you want to use.

15.2

To change the tray: Use the **<↑>** to move the cursor to the "Tray/Posit" field. The "Select tray" dialog window appears.

[Select tray]

No	No smp	first ID	last ID	Status
1	60	101	160	finished
2	60	201	260	finished
3	5	301	306	not compl.
4	25	401	425	ready
5	5	304	504	ready
6				free
7				free
.				free
.				free
17				free

You may either start a new tray or add to any tray with any status except "finished". Move the cursor to the tray you want to use and press **<Enter>**. Move the cursor to an empty position if you want to start a new tray.

The display returns to the "Enter new samples" dialog window. The selected tray number will be in the Tray field. The position assigned will be the first open position on that tray.

C. Entry into the "Ident." field is mandatory.

Patient samples: Enter a unique patient identification number or name. Any letter and number combination up to 20 characters may be used. An off-line barcode reader (optional equipment) may be used to enter the ID. The ID assigned must be unique. If it is not, an audible alert sounds and the message "multiple!!!" is displayed in the "Ident." field. It means that this sample ID is already in the data archive and cannot be used again in this file-formatting period.

QC samples are entered using a "QC code" which represents the ID Code defined for that control in combination with a 2-digit identifier sequence code. The 2-digit sequence identifier may be any combination of the following:

20.1.2.1
20.3

00 through 99
A0 through Z9
0A through 9Z
AA through ZZ

The 2-digit sequence identifier is prefaced by the ID Code defined for that specific control (<Q.C.><Q.C. Setup><Controls>).

For example: One of the defined controls is ACCUCLOT™ Normal and it's ID Code has been defined as ACN. Valid ID entries to signal the AMAX 200 that this is a QC sample are ACN00 through ACN99; ACNA0 through ACNZ9; ACN0A through ACN9Z; and, ACNAA through ACNZZ.

The same QC code cannot be used repeatedly in any given file format period. For example: The first ACCUCLOT™Normal after formatting the file is called ACN00; the second ACN01; the third ACN02. If the QC code entered is not unique, there will be an audible beep and a message that says "multiple!!!" is displayed. It means that this QC code is already in the data archive and cannot be used again in this file-formatting period.

D. Entry into the name, location and note fields is optional. This information may be entered now, never or at your leisure using the patient "Edit" option. Any of these fields may be by-passed by pressing **<Enter>**. Pressing **<F3>** will bypass all three fields and go directly to the test requisition area.

   a. Name: Character limit = 40.

   b. Loc: "Loc" refers to the location of the patient.

18.6

      (1) Type in exact full name of the location (Character limit = 20)
      (2) **<.>** or **<,> <defined location code><Enter>**
      (3) If you don't know the codes, **<.>** or **<,><Enter>** will being up a location code selection list. Move the cursor to the desired location and press **<Enter>**.
      (4) Note: Character limit = 40

E. Move to the test requisition area by using either **<F3>** or <↓>. Tests may be requested in 3 ways:

   a. Enter the Test Code or Test Number.

   b. Using the numeric keyboard, **<+><Enter>** brings up the Test List. Move the cursor to the desired test and press **<Enter>**.

   c. Tests may be ordered as panels. **<F8>** brings up the Panels List. Either enter the panel number or move the cursor to the desired panel and press **<Enter>**.

   Note: Only tests that are included in the active Test Group will be run during processing. Extraneous tests may still be ordered now and then processed without reordering during a different processing period using a different Test Group.

F. There are 3 different ways to continue entering samples:
   a. **<F2>** advances to the next "Ident." field. Enter all ID and requisition information as above.
   b. **<F4>** stores the test combination just selected on the current patient. This test combination will be automatically transferred to every subsequent patient when **<F2>** is pressed. Enter ID information as above. The test combination may be changed at any time by entering the test requisition area and either adding or removing tests. A test may be removed by moving the cursor to that test and pressing **<Space><Enter>** or **<Delete>**.
   c. **<F5>** orders the test combination just selected on the current patient and automatically increments the ID by 1.
   d. When <F5> is pressed, a dialog window opens asking for the total number of samples.

[Multiple samples]

```
N. of samples:
```

Enter the **total number** of **samples** (including the current sample) that are to be numbered consecutively and have the same tests ordered. Complete the request with **<Enter>**. The next available empty position will be displayed.

G. Continue as above until all samples have been entered.

10.5.2 Keyboard Edit of Old Patients

An "Old" patient is one that already has ID information registered in the patient data file. Information may be added or changed. New tests may be requisitioned.

17.2

<Patients><Edit>. The "Edit samples" dialog window will open.

```
Modify sample-ID code:  (ID code)
```

Enter the ID code of the first sample to be edited. Press **<Enter>** to complete. The "Modify samples" dialog window will open. This window is identical to the "New samples" window. It will contain whatever information has already been entered on this sample.

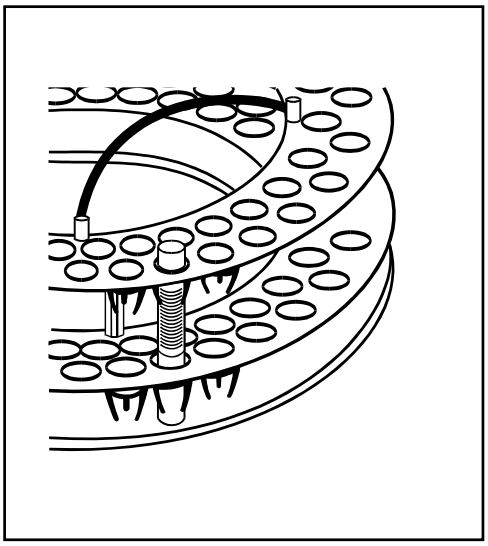
Move through the window and make entries in the same manner as that described above for "New sample addition". All previously entered information may be altered. If the ID code is changed, a confirmation request will be displayed. Confirm (**<y><Enter>**) or deny (**<Enter>**) as appropriate.

ATTENTION!
All printouts on altered ID codes will be marked with an " ***** ".

Tests may be deselected by moving into the TESTS area and placing the cursor over the test to be removed. Press **<Space>** or **<Delete>**.

10.5.3 Position Samples in Sample Tray

A. **Positive Id:** Samples may go anywhere in the tray.



B. **Position oriented**: Samples are positioned according to the assigned tray position number.

   a. To print a load map for the programmed tray: **<Measure><Trays> <Show>**. Move cursor to the appropriate tray and press **<Enter>**.

   b. The positioning of every programmed sample is displayed. Press **<Print Scrn>**.

   c. Position samples in tray according to the load map.

10.6 Start Processing

Processing may begin at any time after samples have been programmed; or, if positive Id and auto-profiling are on, after samples have been placed in the sample tray.

15.4

Prior to starting processing, the following conditions should be checked:

- All stoppers have been removed from sample tubes.
- All lids have been removed from reagent containers that will be accessed during the processing period.
- The cover of the reagent/sample tray storage area is on.
- The cuvette waste bin is not full and that the drawer is closed.
- The cuvette box disposal area is not full.
- The supply of fresh water is adequate.
- The waste water container is not full.
- The supply of Enzyclean is adequate.
- No objects are on the working surface of the instrument or under the dilutor syringe.

10.6.1 Select Test Group

If a Test Group has not already been selected: **<Measure><Test Groups>**. Move the cursor to the **desired group** and press **<Enter>**.

10.6.2 Start

<Measure><Start>

15.4

As soon as the "Start" command is given, the AMAX 200 performs internal checks to ascertain that all working conditions are within specifications. The instrument verifies that all temperatures are within specified ranges; the fresh water reservoir is not empty; the drain container is not full; at least two cuvette boxes are in the chute; and, the lamp is on. Processing will not begin until all conditions are within specifications.

When there are no error conditions, the "Start-Test Group" dialog window is displayed:

[Start-Test Group]

```
Name      :Routine
Group     :4
Reagent   :ROUTINE
      Tests --     Replicate
   1: PT           Single
   2: PTT          Single
   3: FIB          Duplicate
   4:
   5:
   6:
   7:
   8:
   9:
   10:
   11:
   12:
   Confirm  :  YES
```

19.1

A. If the correct Test Group is displayed, press **<Enter>**.
If the Test Group is not correct, press **<n><Enter>**. Go to **<Measure><Test groups>** and select the correct group. Re-start by again pressing **<Measure><Start>**.

B. The instrument next checks for expired reagents. If one or more reagents are beyond the programmed expiration date, the "Expired reagents" window is displayed:

[Expired reagents]

```
Reagent  Lot      expired
ALEXIN   45H6214  3/31/97


Start run?    NO
```

If you want to replace the reagent now, press **<Enter>**. If the reagent has not expired or you don't want to replace it now, respond to "Start run?" with **<y><Enter>**.

ATTENTION!
The reactivity of expired reagents is unreliable. Do not use unreconstituted reagents beyond the listed expiration date. Do not use reconstituted reagents beyond established stability claim limits.

Prepare fresh reagent or start a new unexpired lot number. Update the lot number and expiration date in the appropriate Reagent Definition dialog window

19.4.1

C. If Positive-Id is not active, a dialog window asking for confirmation of the tray will be displayed:

```
Sample tray number  :  #
Confirm  :  NO
```

If the tray number displayed is correct, confirm with **<y><Enter>**.

If the tray number is not correct, press **<F3>** to open the "Select tray" dialog window. Move the cursor to the correct tray and press **<Enter>**. Press **<Esc>** to exit the window and return to the tray confirmation window. Confirm that the tray is now correct by pressing **<y><Enter>**.

Processing begins.

D. If Positive-Id is active, the instrument scans all positions until a sample is found that has unprocessed tests. All subsequent positions defined by the batch size are scanned. Processing begins on the first batch of samples. Scanning of subsequent samples continues while the first batch of samples are being processed. Immediately prior to the processing of a new batch of samples, the samples will be re-scanned. If the re-scanned barcode does not match the barcode as read during the initial scan (indicating a moved sample), the sample will not be processed and the error code message assigned to Error Code 6 will be stored and printed for that sample, e.g. "Barcode error".

18.8.2

E. If a new Test Group has been selected or if this is the first processing period for the Test Group, the instrument starts the processing cycle by checking reagent levels. If one or more essential reagents are below the programmed required minimum volume, processing is interrupted. "Reagent refill" will be displayed in red on the bottom of the Main Menu screen. An audible alert will sound. All reagents must be present if Positive Id is active.

   a. Turn the alarm off by pressing <Alt-F2>.

   b. Open the "Reagent overview" window: <Overview><Reagent>.

   c. Reagents with insufficient volumes will be flashing red. Note that if the Enzyclean level is below the required minimum, none of the other reagents will be checked. Replenish reagents and Enzyclean as necessary.

ATTENTION!
Continued repeated addition of new reagent to old reagent may lead to changes in the reagent composition that may change its reactivity. It may also lead to microbial contamination, which will seriously compromise reagent stability. Reagent containers that are reused should be thoroughly decontaminated with 10% bleach, rinsed in tap water, rinsed in DI water and dried prior to reuse.

ATTENTION!
Enzyclean is the recommended system cleaner. To avoid compromising precision and accuracy, water or other unrecommended fluids should not be used.

d. Replace cover when finished. Restart processing with **<Measure><Start>**.

The cover to the storage area must be on at the start of processing. Although it may be removed after processing has begun, it must be in place before processing will start. To facilitate temperature regulation within the storage area, it is recommended that the cover always be on except when actually working in the area. If the cover is off at the start of processing, the following message will be displayed:

```
WARNING       Close lid
```

Replace cover. The message will disappear and processing will begin.

10.7 Pause, Stop and Abort

Processing may be interrupted or terminated at any time.

- **Pause**. Interruption of processing for a brief period of time. Processing is resumed on command at anytime within an allotted time interval.

15.6

- **Stop**. Sampling is stopped but tests currently in progress are completed (soft stop).
- **Abort**. All processing is terminated immediately. All tests in preparation or incubation are cancelled (hard stop). Tests in the measuring wells are completed.

10.7.1 Pause

The primary use of "Pause" is when adding samples or reagents. This allows addition without having to dodge the robot or keep up with moving sample/reagent trays. The instrument will automatically go into "Pause" mode when processing is started on samples added during a processing period.

To initiate Pause: **<Measure><Pause>**.

Pause is a limited time procedure. The instrument will enter the "Pause" mode only when there is enough time remaining before the instrument has to do something. The screens that appear are dependent on what the instrument is doing when <Pause> is selected.

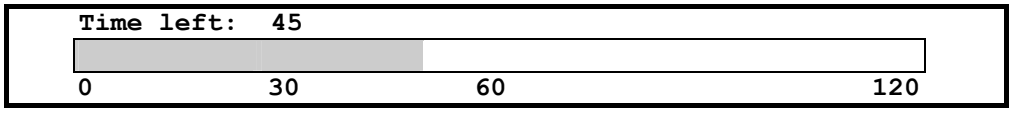
There will be times when there isn't enough time for the instrument to pause processing before it has to do something else. In that event, the message "Run cannot be paused!" will be displayed.

```
Run cannot be paused!
```

After a short time delay, this screen will be replaced by the "Please wait . . ." screen.

```
Please wait . . .
```

When there is time for you to do something, a countdown time bar screen will be displayed showing how much time that you have to accomplish your work.



The robot will move to the far right. Any work must be done within the allotted time frame. The time will count down. An audible alert will sound when the time is at 10 seconds. When work is completed, press **<any key>** to end the "Pause" period. If "Pause" is not ended within 5 seconds after time expires, processing will be aborted. If the time initially allotted is not enough for you to do your work, press **<any key>** to end the "Pause" procedure and try again later.

WARNING!
The robot will immediately come left when <any key> is pressed. Work must be completed and the operator out of the area prior to ending “Pause”.

10.7.2 Stop

Sampling is stopped. No new tests will be started. Tests in progress will be completed. At the completion of testing, the status will go to “Ready”.

To initiate a “Stop”: **<Measure><Stop>**.

10.7.3 Abort

All processing stops. No new tests will be started. Tests currently in preparation or incubation will be terminated. Tests in the measuring wells will be completed.

To initiate an “Abort”: **<Measure><Abort>**.

An alarm immediately sounds. Turn off sound by pressing **<Alt-F2>**.

As soon as <Abort> is pressed, the “Abort confirmation” screen is displayed.

```
Confirm: NO
```

If you do want to stop all processing, press **<y><Enter>**. If you do not want to lose all testing currently in progress, press **<Enter>** to deny the abort request.

Any cuvettes remaining in the incubation rail will be transported to the first optical measuring well and discarded.

10.8 Stat Testing

Up to 8 Stat samples may processed at one time. Positive Id is not used. Barcodes can be entered using an offline scanner. Only tests that are in the currently active Test Group may be ordered (19.1.1). The Reagent Layout assigned to the currently active Test Group must have assigned Stat positions (19.3.1.c).

16
19.1.1
19.3.1.C

10.8.1 Stat Requisitioning

A. **<Stat><#. Position>**
The “Stat” window for the selected position number is displayed.

[Stat #]

```
Ident.    : 123456
Name      :
Loc       :
   --------- TESTS ---------
PT                ordered
PTT               ordered
> FIB <
```

B. Entry of a sample ID is mandatory. For controls, use the defined Control ID plus a 2-digit sequence number. Entry of name and location is optional. Type in **<Sample ID><Enter>** or (**<Control ID + 2-digit identifier><Enter>**). A barcode number may be entered as the ID. An optional offline barcode reader may be used to enter the ID.

C. Entry of "name" and "location" is optional. Type in the **<name>**. Type in the **<exact location code>** or press **<.><Enter>** to bring up the "Location codes" pick list.

D. Using the cursor keys, move into the "TESTS" area. The only tests that will appear are those assigned to the active Test Group. Move the cursor to the appropriate test(s) and press **<Enter>**. Pressing **<Enter>** with the cursor over a test that has been ordered will deselect the test.

E. Press **<Esc>** to complete the request.
   a. If currently processing, one of the "Pause" screens will be displayed.

      When the instrument is at a point where it can interrupt processing a screen will appear showing the time left before the instrument must re-start processing. Make a mental note of the time and press **<any key>** to clear the screen. A confirmation to "Start Stat sample now?" is requested. The robot moves to the far right. Position Stat sample into the programmed position in the outside ring of the Reagent Tray. Close cover over the storage area and confirm that the Stat sample is ready for processing by pressing <Enter>. If for any reason you are not ready to start processing on the Stat sample, deny the confirmation request by pressing **<n><Enter>**.

   b. If the instrument is not currently processing, the confirmation to "Start Stat sampling now?" is displayed. Press <Enter> to begin processing. A request for confirmation of the sample tray is displayed. Press **<Esc>** to confirm the displayed tray number. If the tray number is not correct, enter the correct tray number. Confirm with **<Esc>**.

F. Once a Stat position has been programmed, the position will display in red in the "Reagent overview" screen.

10.8.2 Viewing and Printing Stat Results

Stat results may be viewed as they are being processed. Re-enter the "Stat" menu and select the Stat position whose results you want to view. As tests are completed, the result will replace the comments. At the completion of testing on the sample, a quick printout may be obtained by pressing **<Print Scrn>**.

10.8.3 Emptying Stat Positions and Transferring Sample to Archive

Once a Stat position has been used, it is locked and cannot be re-used until the Stat sample is transferred out of the Stat files and into the patient archive files.

A Stat sample cannot be deleted while it is processing. Once processing on the Stat is completed, it may be deleted to open the position to accommodate additional Stat samples. Press **<F10>** to delete the Stat sample from the Stat file. Confirm the **"Delete Stat sample? NO"** with **<y><Enter>**. All ID and result information is transferred to the patient archive files. Once the information has been transferred to the archive files, the sample may be recalled and printed using either the "Result list" or "Report" option.

10.9 Overview

The "Overview" options provide real-time oversight of exactly what is happening during processing. The different processes that may be observed are:

13

1. Total operation overview: **<Overview><CS>**
2. Reagent usage levels: **<Overview><Reagent>**
3. Result review: **<Overview><Results>**
4. Sample staging: **<Overview><Samples>**

10.10 Graphic Mode

The "Graphic" mode allows real-time observation of photo-optical and chromogenic reactions. The graphic reaction representations are stored in the patient data file and may be retrieved later and printed.

15.5

The default setting for "Graphic" is OFF**. Routine operation in the graphics mode is not recommended.** Large amounts of storage space are required and throughput is slowed. It is useful when developing new tests and may provide useful information when troubleshooting.

To activate the "Graphic" mode: **<Measure><Graphic><F1>**.

The graphic mode will remain active until turned OFF or until the operating program is exited and re-entered. To deactivate: **<Measure><Graphic><F6>**.

10.11 Repeat Testing

Any test that has been processed may be repeated. The "Repeat" command deletes any previously registered result for the selected test.

17.4

In addition to selecting samples for repeat testing, new tests may be requested on samples already identified and new samples may be added and tested.

<Patients><Repeat>. The "Repeat test" dialog window opens. Enter the Test Code, Test **Number** or press **<+><Enter>** to bring up a test listing. Move the cursor to the test to be repeated and press **<Enter>**. The "Repeat test" entry window opens.

[Repeat test]

```
          Test: PT

1: 223            16:
2: 224            17:
3: 419            18:
4: *595           19:
.                 .
.                 .
15:               30:
```

Type in the ID codes of the samples to be included in the repeat processing:

- Previously processed tests may be repeated;
- Additional tests on old samples may be requested; and,

- New samples (not already registered in the patient archive) may be added. New samples will be marked on the repeat listing with an " * ". New samples must be assigned a tray position (<Patient><Edit> or <Tray><Load>) prior to starting processing.

ATTENTION!
If "Position oriented" is active, "old" samples are **not** moved to new positions. "New" samples must be placed in their assigned tray position. If "Positive-Id" is active, samples may be moved to a position closer to the beginning of the tray.

If the desired Test group is not active, select the appropriate Test Group (**<Measure><Test groups>**). Start processing (**<Measure><Start>**).

If "Positive-Id" is off, a load map of the repeat worklist is displayed with the samples scheduled for repeat highlighted in red. Assure that the appropriate samples are in the highlighted positions. Press **<Enter>** to begin processing. If you decide not to start processing, press **<Esc>** to abort the repeat procedure.

10.12 Printout of Results

18.9.2

If the "Print protocol" option is active, results are printed out real-time. The results are printed out as soon as all requested tests currently being processed on a sample are completed. Requested tests that are not in the test group selected will be printed out according to the definition of Error Code 0.

ATTENTION!
Real-time results are not printed in ID sequence. Test results are printed out in the order in which they are completed. Always check the ID prior to reporting any results.

The "Result list" option provides a means of printing an ID sequenced collated result list. All results on a sample are printed together. Along with ID information, only the final result on each test is printed. Stat samples must be removed (deleted) from the Stat files in order to be included in the "Result list".

17.8

1. **<Patients><Result list>**. The "Result list" dialog window opens.

[Result list]

```
Loc      :
from     :
to       :
Confirm  :  NO
```

The "Loc", "from", and "to" fields are used to sort the results. Only the inclusive results specified will be printed.

2. Entry into the “Loc” field is optional. If a location is specified, only the inclusive results (between “from” and “to”) for that location will be printed. Location codes are entered in the same manner as described for “New sample addition” (**<,>** or **<.><Enter>** brings up location listing). To by-pass “Loc”, press **<Enter>**.
3. Enter into the “from” field: The ID code of the first sample to be included in the printout.

> **ATTENTION!**
> Failure to make a valid entry into this field will result in printout of all results from the beginning of the patient archive up to the specified “to” ID.

4. Enter into the “to” field: The ID code of the last sample to be included in the printout.

> **ATTENTION!**
> Failure to make a valid entry into this field will result in printout of all results from the specified “from” ID to the end of the patient archive.

5. Confirm that all entries are correct with **<y><Enter>**.

10.13 Evaluation of QC Results

QC results are evaluated during processing according to the Westgard Rules enabled in the QC File.

If the alarm has been enabled to provide an audiovisual alert when a rule violation occurs, the “Q.C. Error” message box indicating which rule or rules have been violated will be displayed. The QC status indicator at the far right top of the status bar, will display “QC Er” in red.

20.1
20.2
20.1.1.3

QC results may be accessed, reviewed and edited at any time by pressing **<Q.C.><Q.C. charts>**.

The thumbnail charts for all active QC files will be displayed. Use the page down key to move to the next page of charts and the page up key to go back to the previous page of charts. Individual charts may be examined more closely by using the **<Page Up, Page Down and Arrow Keys>** to move to a **<specific chart>** and then pressing **<Enter>**.

20.3.1
20.3.2

10.14 Printout of Patient Reports

A formatted formal report may be printed. Stat samples must be transferred to the archive before a report may be printed.

<Patients><Report>. A dialog window similar to the "Print results" window will appear.

```
Loc.   :
from   :
to     :
All    ?  NO
Graphic  ?    NO
Confirm  :    NO
```

17.10
18.8

1. Entry into the "Loc", "from" and "to" fields is the same as that described in "Printout of results". The same "from" and "to" cautions apply.

10.12

2. The "All" option is used to differentiate between previously printed reports and unprinted reports.

   To printout all inclusive reports, regardless of whether or not they have been previously printed, press **<y><Enter>**.

   To printout only those inclusive reports that have not yet been printed, press **<Enter>**.

3. When the "Graphic" mode was active during processing optical tests, the graphic reaction representation may be printed out along with the report.

   Press **<Enter>** to confirm that a graphic printout is not wanted. If a graphic printout is desired, press **<y><Enter>**.

4. Confirm that all entries are correct by pressing **<y><Enter>**.

10.15 Errors During Processing: Non-Fatal

The AMAX 200 constantly monitors working conditions during processing. If working conditions deteriorate, these are immediately registered. An audible alert sounds and the "CS-Status" window automatically appears on the screen. The condition that is out of specification will be in a red field.

Clear the alarm by pressing **<Alt-F2>**.

Non-Fatal, operator-correctable errors are:

- Fresh water low (sys. fluid – Input);
- Waste container full (sys. fluid – Output);
- Too few cuvette boxes (Cuvettes – Input); and,
- Cuvette tray waste full (Cuvettes – Tray waste).

When one of these error conditions occur, you have **5 minutes (300 seconds)** to correct the error. The time elapsed since the error was registered is displayed beside the question "Continue? Y/N". If the condition is not corrected and the question is not answered within 5 minutes, processing will stop.

The instrument allows itself 5 minutes to correct temperature errors. The warning will automatically cancel if temperature adjustment is achieved within 5 minutes.

10.16 Errors During Processing: Fatal

If an error occurs which may affect the quality of the results, processing is immediately aborted.

If an unresolvable mechanical or software system error occurs, processing is immediately aborted. A message describing the error will be displayed at the top of the screen:

> Error Robot <133> Hdw. error. Switch system off and on again. Carry out PC reset.

Before switching the instrument off, record the module causing the error and the error number code. If the situation does not resolve itself, this information will be of assistance in resolving the condition.

> **WARNING!**
> Do not switch OFF and ON rapidly. Wait 10-15 seconds after switch OFF before switching ON.

While the instrument is OFF, if the error involves the robot, sample/reagent tray, cuvette or dilutor modules look at these areas to see if there is a visible cause for the error. Correct as necessary. Some of the possible causes are:

1. **Robot Error**
   A. Obstruction within area is restricting movement. Remove obstruction.
   B. Lid of storage area not positioned correctly. Reposition so that the notch straddles the guide.
2. **Cuvette Error**
   A. Cuvette box inserted backwards (arrows pointing out of the chute). Reposition box with the arrows pointing into the chute.
   B. Cuvette box inserted upside down. Turn box over so that the arrows are on the top and pointing into the chute.
   C. A cuvette in the first row of cuvettes is not aligned correctly and transfer mechanism is unable to deliver it into the incubation rail. Realign if possible or remove offending cuvette. If this error occurs repeatedly with this cuvette box, remove box and discard.
3. **Reagent/Sample Tray Error**
   A. Trays are not positioned correctly. Alignment holes on both trays must be over the guide pins. Reposition.
   B. Obstruction within storage area is interfering with movement. Remove obstructing object.
4. **Dilutor Error**
   A. Obstruction under the dilutor is interfering with down movement of the syringe plunger. Remove obstruction.

After correcting any observable problem, switch the instrument ON. During power ON, the system automatically goes through a system reset. This often corrects unobservable problems.

As soon as the operating program restarts, any cuvettes that were in process in the incubation rail will be automatically removed and discarded. If the problem was in the

cuvette module, observe this process carefully to verify that the condition has been corrected.

Proper functioning of the cuvette module may also be checked by using the **"Transfer cups"** command. Open the **"Service"** menu. Move the cursor to **"Transfer cups"** and press **<Enter><Enter>**. Enter the number (1-400) of cups to transfer (2-3 is usually an adequate function check if the problem occurred in the middle of a row but may require more than 10 if the problem occurred when a new cuvette row was delivered to the transfer row).

14.3

Re-start Processing. **<Measure><Start>**.

If the same error re-occurs repeatedly, call Sigma Diagnostics Technical Service (1-800-325-0250) for assistance in resolving the problem.

WARNING!
Internal instrument repair work should only be performed by authorized service personnel.

10.17 Shutdown

If the AMAX 200 will be OFF for more than 8 hours, a 5-cycle system wash is recommended prior to powering down. This will assure a clean system.

<Service><Wash><Enter><Enter><5><Enter>

A 5-cycle wash will commence.

Shutdown is accomplished using the "End" menu. Access to this menu is denied during processing.

There are several exit conditions which must be met prior to shutdown:

1. Empty Stat positions. If Stats have been programmed, go into the appropriate **<#. position>** and delete with **<F10>**. All ID and result information is transferred to the archive files. If any of the Stat positions contain samples which are unprocessed or have pending results, the "Append-Stat" window will appear. These samples and/or tests may either be completed now or after re-starting the operating program.
2. If interfaced to a host computer, check the host status by pressing **<Alt-F3>**. If the data link is active, wait until data transfer is completed. Alternatively, observe the Lis status message displayed in the right hand corner of the status bar. A blinking message indicates that the data link is active. Wait until the status changes to the message Lis (black on white background).
3. Check contents of the printer buffer by pressing and holding **<Alt>**. If there is unprinted data in the printer buffer, <F8> will be displayed as a function key option. If the buffer is empty, <F8> will not be displayed as an option.

   The most common reasons that the buffer is not empty is that the printer is off, not on-line or has run out of paper. If you want to printout the buffer, correct whatever is wrong as necessary. Printout will occur automatically.

   If you want to see what is in the buffer before printing; or, do not want to print the contents of the buffer, press **<Alt-F8>** to display the contents of the buffer. The first

page of data contained in the buffer is displayed. Press **<Enter>** to display any subsequent pages. If you do not want to print the buffer, press **<Enter>** or **<Esc>**. A cancellation request confirmation ("Delete? NO") is displayed at the bottom of the page. Data may either be printed or deleted.

To print the buffer contents, correct any printer error condition. Buffer will be printed automatically.

If you do not want to print the buffer contents, confirm the deletion request with **<y><Enter>**.

When all exit conditions have been met, the operating program is exited. The DOS screen is displayed with the currently active drive and path.

Once the DOS screen is displayed, the instrument may be powered down by pressing the OFF/ON switch. If at the DOS screen, you may re-enter the operating program by typing in **<a><Enter>** or with one of the valid DOS parameters. If one of the DOS parameters is entered, when the operating program is re-entered, the selected DOS parameter will be active.

12.4

11 MEASUREMENT PRINCIPLES 11-1
11.1 MECHANICAL MEASUREMENT (BALL METHOD) 11-1
11.2 OPTICAL MEASUREMENT 11-3
11.3 KINETIC OPTICAL MEASUREMENT (CHROMOGENIC) 11-5

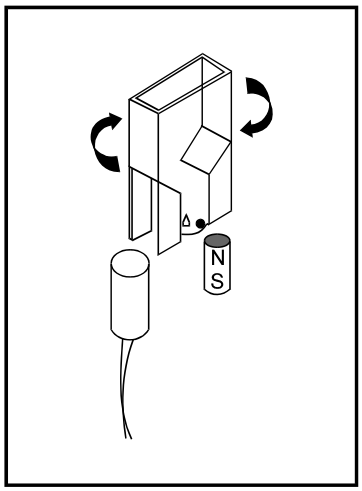
The AMAX 200 offers three alternative ways to measure test reactions:

1. Measurement of clotting endpoint by mechanical principles.
2. Measurement of clotting endpoint by optical principles.
3. Measurement of chromogenic enzyme and immunological assays by optical principles

11.1 Mechanical Measurement (Ball Method)

Mechanical measurement methods depend on the physical formation of fibrin strands that attach to a moving mechanical device which ultimately either completes or opens an electrical circuit.

The Amelung ball method utilizes a special cuvette that contains a stainless steel ball. The cuvette rotates. The ball is held in a steady state position by a magnet.



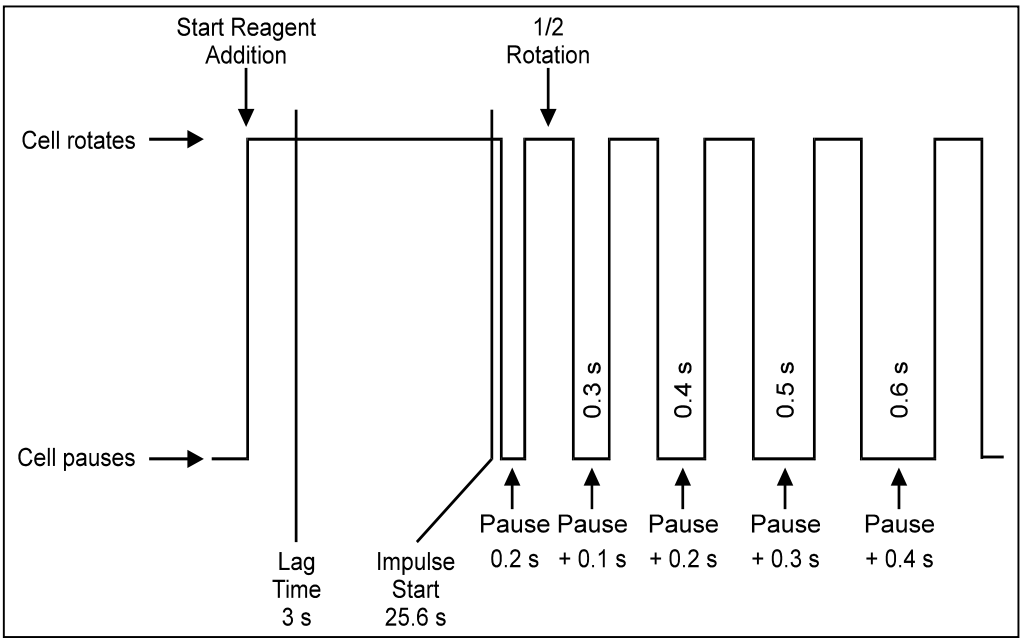
Sample and reagent are dispensed into the cuvette that is then automatically inserted into one of the mechanical measuring wells.

With the addition of the starting reagent, the cuvette starts to rotate around its longitudinal axis while the steel ball is kept in its predetermined position by a magnet.

At the start of coagulation, the fibrin filaments drag the ball away from its steady state position. This change of position releases an impulse in the magnetic sensor that automatically stops the time measurement.

The elapsed time from the addition of the start reagent up to the beginning of fibrin formation is measured. Any test that has fibrin formation as its endpoint may be determined. When used in conjunction with appropriate reagents, the sample may be either plasma or whole blood.

An additional feature of the principle of mechanical operation is the impulse mode. A moving mechanical device may produce two artifactual effects. The first effect is a prolongation of clotting time caused by the breakdown of fragile fibrin formations by the constantly moving mechanical device. The second effect is a shortening of clotting time caused by spurious activation (“whipping action”) resulting from the constantly moving mechanical device. This effect is particularly noticeable in samples deficient in factors II and V. The AMAX 200 uses intermittent rotation to minimize any artifactual effects caused by a continuously moving mechanical device. The measuring cell rotates continually until the rotation is paused at a defined time interval. From this time on, the cell pauses after every half rotation. Each pause period is 0.1 second longer than the preceding pause period. This pause allows fragile fibrin formations to organize and minimizes any “whipping action”. The “impulse time” is defined for every mechanical test procedure, which assures optimal performance based on the reaction characteristics of each test.



Impulse Time Entry	Start of Impulse Time
< 25.6 Seconds (1-25)	Approximately 1 second after delay time
> 25.6 < 51.2 seconds (26-51)	25.6 seconds
> 51.2 < 76.8 seconds (52-76)	51.2 seconds
> 76.8 < 102.4 seconds (77-102)	76.8 seconds
Continuing increments of 25.6 seconds	Continuing increments of 25.6 seconds

11.2 Optical Measurement

The basic premise of optical measurement systems is that as coagulation takes place the optical density increases thereby decreasing the transmission of light. The AMAX 200 measures the initial absorbance and monitors the absorbance change over time. Because the change in absorbance between the initial reading and the final reading is used to calculate the results, the effect of adverse sample conditions such as lipemia or icterus is minimized.

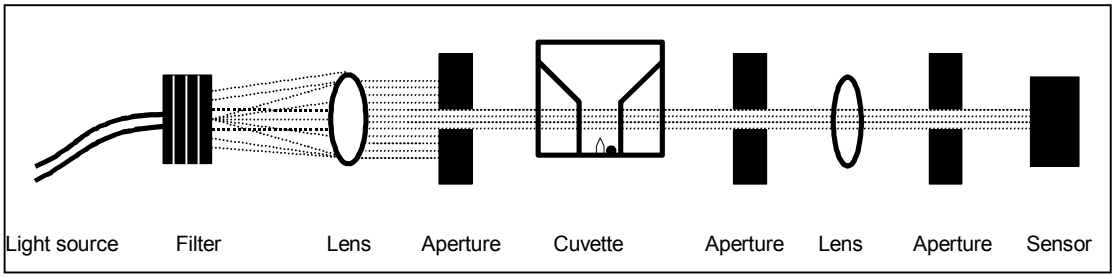
The AMAX 200 has a programmable delay time that is designed to eliminate false noise interference that may precede true clot formation.

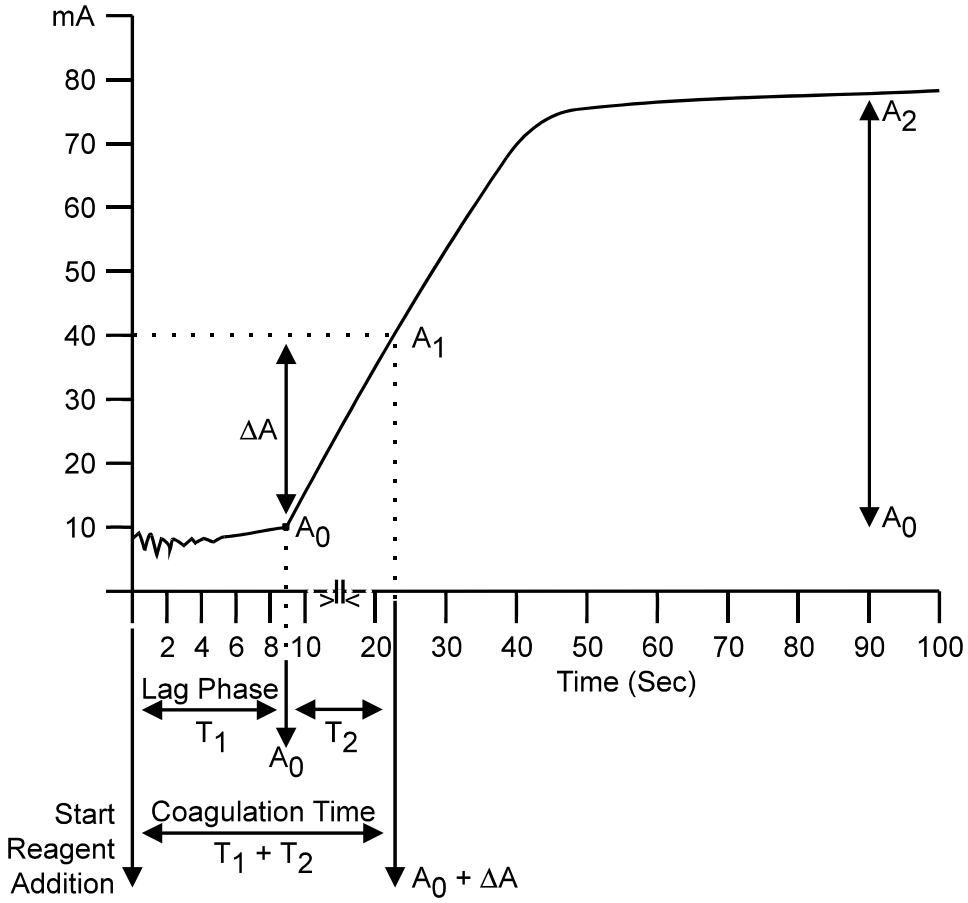
The same cuvette containing a stainless steel ball is utilized for optical measurement. The stainless steel ball is below the light path and does not interfere.

Sample and reagent are dispensed into the cuvette that is automatically inserted into one of the optical measuring wells.

With the addition of the starting reagent, measurement timing begins.

A light beam (405 nm) passes through the cuvette. A sensor that records any change in the absorbance of the reaction mixture constantly monitors the beam. As coagulation occurs the optical density of the reaction mixture changes causing a change of the absorbance rate. As soon as the predetermined programmable threshold rate change is reached, time measurement is stopped.





A_0 = Optical density after lag time or at flex point
A_1 = A_0 + defined ΔA
T_1 = Time from addition of start reagent to A_0
T_2 = Time from A_0 to time when defined ΔA reached (A_1 time)
Coagulation time = $T_1 + T_2$
A_2 = Optical density at 90 seconds
Derived Fibrinogen (mA) = $A_2 - A_0$

11.3 Kinetic Optical Measurement (Chromogenic)

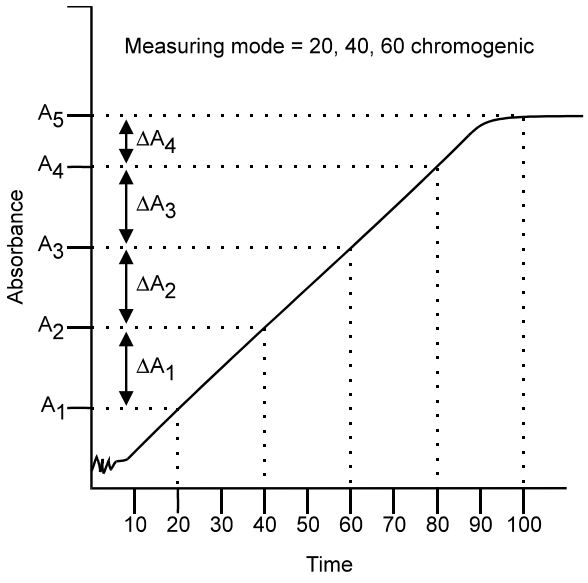
Enzymes react with specific peptide sequences. A specific amino acid sequence determines the cleavage site. In chromogenic analyses, a synthetic amino acid sequence serves as the substrate for a specific enzyme. A chromophore is used as an indicator tag. The active-site sequence is coupled to an optically active chromophore. The enzyme cleaves the bond between the active site and the chromophore releasing the chromophore tag. The optical characteristics of the free tag are significantly different from those of the coupled tag resulting in an optical density change that may be measured. The rate of release of the chromophore tag quantifies enzymatic activity.

The same cuvette containing a stainless steel ball is utilized for chromogenic measurement. The stainless steel ball is below the light path and does not interfere.

Sample and reagent are dispensed into the cuvette that is automatically inserted into one of the optical measuring wells.

A monochromatic light beam (405 nm) passes through the cuvette. A sensor that records any change in the absorbance of the reaction mixture constantly monitors the beam.

With the addition of starting reagent, the rate of absorbance change is measured at predetermined intervals. The change is calculated in mE/min. The concentration is calculated by comparison to a standard curve.



$A_2-A_1 = \Delta A_1$

$A_3-A_2 = \Delta A_2$ $\quad \Delta A_1 = \Delta A_2$ Reaction linear

$A_4-A_3 = \Delta A_3$ $\quad \Delta A_2 = \Delta A_3$ Reaction linear

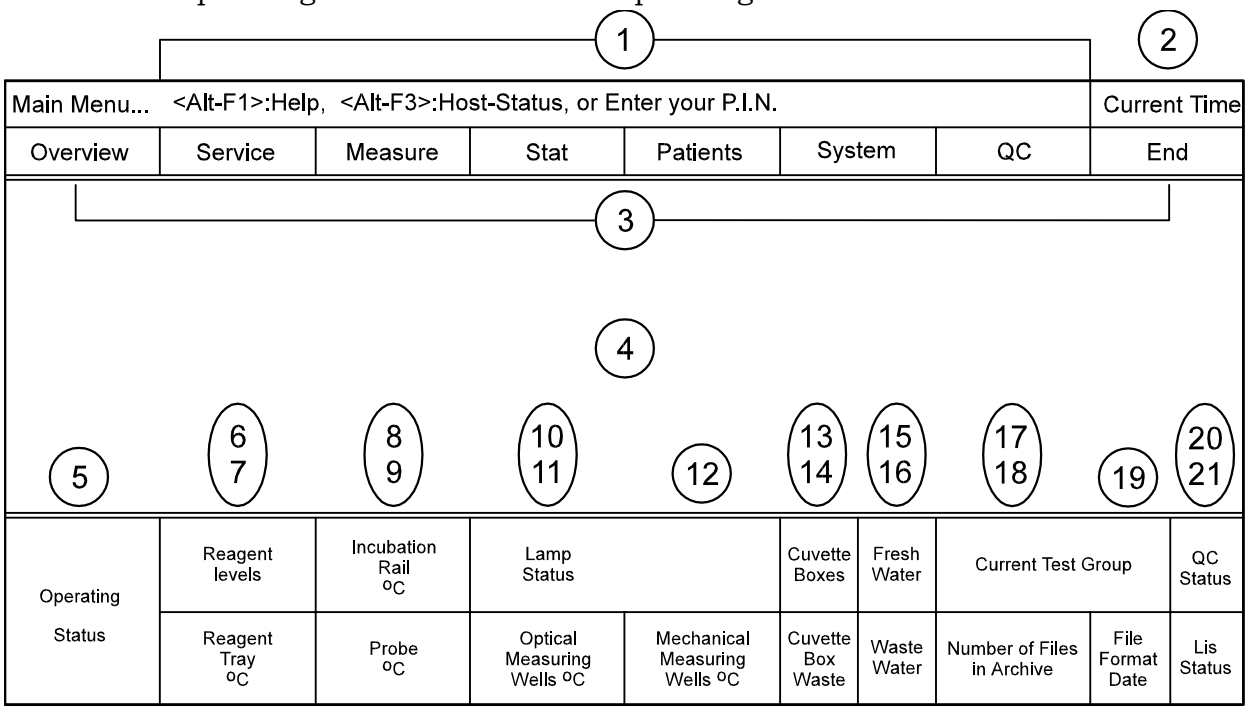
$A_5-A_4 = \Delta A_4$ $\quad \Delta A_3 > \Delta A_4$ Reaction non-linear

A measuring mode set to read at 20, 40, 60 seconds will be measuring within the linear range

12 MENUS OVERVIEW 12-1
12.1 MAIN MENU 12-1
12.2 <ALT>-FUNCTION KEYS 12-3
12.3 <CTRL-F1>-FUNCTION KEYS 12-5
12.4 DOS PARAMETERS 12-5
12.5 MENUS OUTLINE 12-10
12.6 MENUS FLOWCHARTS 12-14

12.1 Main Menu

Whenever the AMAX 200 is activated, the Main Menu is displayed. The Main Menu provides access to all of the operation-associated menus. It also indicates the status of the critical operating modules the critical operating modules.



Key	Description	Indicates
1	Function key area	Lists certain active function keys and submenus associated with those keys. The keys displayed change with menu topic selection.
2	Current time	Displays the time according to the PC battery-operated clock. Time is set in DOS. To set the time to 10:30 PM: C:>TIME 10:30P
3	Main Menu topics	Access area to all main menu topics. All menus may be accessed by moving cursor to topic and pressing <Enter> or by pressing the color-highlighted letter for each topic.
4	Window display area	Display area for menus, submenus and messages
5	Operating Status	Displays the current operating status of system. Provides information as to whether the instrument is ready to operate, is busy, is waiting for an incubation to end. If red highlighted, an error condition exists. Green highlighted indicates no error conditions.
6	Reagent levels	Flashing red field when reagent below minimum volume level
7	Reagent/Sample Tray area	Indicates temperature of reagent/sample tray area. Flashing red field when above or below set limits
8	Incubation rail temperature	Indicates the temperature in the incubation rail area. Flashing red field when above or below set limits
9	Probe temperature	Indicates the temperature of the probe. Flashing red field if above or below set limits
10	Lamp status	Indicates whether the lamp is ON or OFF. Red with “Wait” if hasn't reached operational output

Key	Description	Indicates
11	Optical measuring wells	Indicates the temperature in the optical measuring wells. Flashing red field if above or below set limits
12	Mechanical measuring wells	Indicates the temperature in the mechanical measuring wells. Flashing red field if above or below set limits
13	Cuvette boxes	Indicates whether the supply of cuvette boxes is OK. Flashing red field if less than 2 boxes present
14	Cuvette waste	Indicates whether the cuvette waste chute is OK. Flashing red field if full
15	Fresh water	Indicates whether the supply of fresh water is OK. Flashing red field if below sensor level
16	Drain water	Indicates whether the waste water level is OK. Flashing red field when above sensor level
17	Current test group	Displays the currently selected test group
18	Number of files in Archive	Displays the number of files entered into patient archive since last file format
19	File Format Date	Displays the date of last file format
20	QC status	Indicates QC evaluation status of last run. Red field with “QcErr” if one or more QC samples violated enabled evaluation rules. Field will remain red until the out-of-range control has been repeated.
21	Lis	Display of host interface status. Lis (black on white) = OK. Lis (black on red) = error in last transmission. Exp (blinking yellow on white) = data being transmitted. Exp (blinking yellow on red) = data being transmitted after previous error. Imp (blinking yellow on white) = data being received. Imp (blinking yellow on red) = data being received after previous error.

All of the operations of the AMAX 200 start at the Main Menu. There are 8 main topic areas. Each of these along with their associated submenus will be covered extensively in the section indicated.

Overview	Section 13	Monitor functions
Service	Section 14	Utility tasks
Measure	Section 15	Processing tasks
Stat	Section 9	Quick Start operating mode
	Section 16	Stats - Normal operating mode
Patients	Section 17	Identification and test requisitions
System	Section 18	Operating protocols
	Section 19	Parameters
QC	Section 20	Quality control functions
		Patient Distribution statistics
End	Section 21	Exit to DOS

12.2 <Alt>-Function Keys

To display a listing of the functions assigned to the <Alt-F#> Keys: Press and hold down **<Alt>** Key.

[<Alt>-Functions]

```
F1  : Help
F2  : (Sound off)
F3  : Host-Status
F4  : AMAX200-Status
F5  : Command log
F6  : (Sign On)
F8  : (Printer buffer)
F9  : Color set-up #1
F10 : Color set-up #2
```

Pressing **<Alt> + <the appropriate F Key>** will either perform a task, bring up a display window, or open a dialog window.

F2, F6 and F8 are only displayed under certain operating situations. These will be discussed in more detail below.

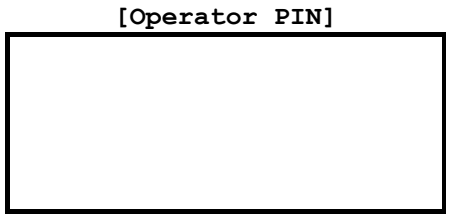
1. < Alt-F1>: **Help**. Displays an interactive Online Help Text.
2. <Alt-F2>: **Sound off**. An alarm will sound whenever there is an error condition that needs prompt attention by the operator. To turn the sound off, press **<Alt-F2>**.
3. <Alt-F3>: **Host-Status**. Opens a window displaying the status of an interfaced host computer (LIS system).
4. <Alt-F4>: **AMAX 200-Status**. Opens a window displaying the status of the different operating modules. These are the same status indicators that are displayed on the bottom of the Main Menu screen. When one of the status indicators is red on the Main Menu, the corresponding temperature or other indicator will be also red and flashing in the AMAX 200-Status window. This window is helpful as a guide to quickly identify the cause of a monitor alarm. The different modules are identified along with the monitored temperature or other status indicator. The instrument during certain error conditions will occasionally spontaneously open this window. If a hard-copy printout is needed, this window and many others may be printed by pressing **<Print Scrn>** when the window is being displayed.

[AMAX200 – Status]

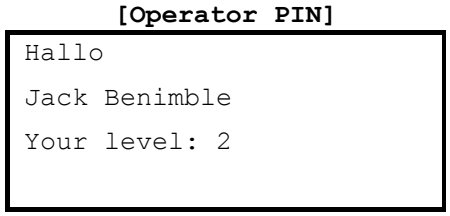
Temperature	Sample/Reagent	14.9
	Probe	37.7
	Opt. Meas.	37.4
	Mech. Meas.	37.0
	Incubation	37.4
	Cooling	40.8
Photom. lamp	Status	on
	Condition	OK
Sys. fluid	Input	OK
	Output	OK
	Wash Cycles	
Cuvettes	Input	OK
	Tray waste	OK

5. <Alt-F5>: **Command log**. Opens a multi-page listing of all commands given to the instrument. May be useful when troubleshooting or tracking work patterns.

6. <Alt-F6>: **Security sign on**. Only displayed when the security system has been enabled. Opens up an "Operator PIN" entry screen.



The cursor will be flashing in the center of an empty box awaiting entry of an Operator PIN. Once the PIN has been entered the "Sign-on greeting" screen is displayed.



7. <Alt-F8>: **Printer buffer**. Only displayed when there is something in the printer buffer waiting for printout. Whatever is in the buffer will be displayed. The most common triggering events are failure to turn the printer ON, printer not on-line, or printer out of paper. The buffer may either be printed by correcting any conditions resulting in the inability of the printer to print or the buffer may be deleted. To clear the contents of the printer buffer press **<Esc>** once; or **<Enter>** repeatedly until the last page of the contents is displayed followed by an additional **<Enter>**. The message **"Delete? NO"** will appear at the bottom of the screen. Press **<y>** followed by **<Enter>** to confirm. To exit without emptying the printer buffer, press **<Enter>**. To print the buffer contents, correct any condition disabling the printer. Buffer contents will be printed automatically as soon as the disabling condition is remedied.

8. <Alt-F9>: <Alt-F10>: **Color set-up #1 and #2**. The color set-ups define how everything looks on the screen. The colors have been chosen very carefully to assure that information, warnings and other items are shown clearly. Change with caution, keeping in mind that a change in color may have undesirable effects.

12.3 <Ctrl-F1>-Function Keys

Pressing **<Ctrl-F1>** displays the "Channel Statistics" monitor screen. The screen displays the results from the previous processing period for each measuring channel. The number of tests with a time less than 4.5 seconds, a time greater than the timeout (reported as NC), the total number of tests run in each channel, the mean value of all tests in each channel and the CV of those measurements is displayed. This screen is extremely helpful as a troubleshooting tool.

[Channel Statistics]

Channel	<4.5	∞	n	ϕ	CV
Opt.1	0		0	0	
Opt.2	0		0	0	
Opt.3	0		0	0	
Opt.4	0		0	0	
Mec.1	0	2	17	56.6	99.4
Mec.2	0	2	17	60.7	77.0
Mec.3	0	2	16	61.9	87.0
Mec.4	0	1	16	60.8	92.5

12.4 DOS Parameters

The DOS parameters are used to instruct the AMAX 200 to operate in ways different from the standard operating program. The DOS parameters are used to customize the performance of the AMAX 200 to suit the individual laboratory needs or for a particular one-time purpose. Some of the parameters are designed for use only by service engineers during troubleshooting. A particular parameter may be entered from the C:\ > prompt which will activate the parameter for this start-up only; or, an amax.ini file may be created which will activate the parameter(s) every time the operating program is entered.

To view the available valid parameters:

1. Exit the operating program. **<End><Yes><Enter>**
2. The C:\AMAX> prompt is displayed. **<amax><space><amax><Enter>**
3. The following listing is displayed:

```
Invalid parameter AMAX
Valid parameters are: DEMO
                      ITCHK
                      AUTOLAMP
                      AMAX=USEPOOL
                      AMAX=TESTREAD
                      AMAX=NOREPEAT
                      AMAX=TEST AMAX=NONULBC
                      HOST=nn
                      HOST=DUMP
                      HOST=NORESEND LPT=HP
                      PCL=n
                      DUMP=n
                      E=X2
                      NOBCCHK
                      NOREFILLTANK
```

ARCPRIO
STOPONQCERR
NOTANKCHECK

C:\AMAX>

Any of the DOS parameters may be activated permanently by creating a “amax.ini” file. To create the amax.ini file:

1. Exit to C:\AMAX> prompt. **<End><Yes><Enter>**
2. At the C:\AMAX> prompt type **<edit><space><amax.ini>Enter>**
3. The MS-DOS Editor program is entered with the cursor at the top line ready for entries. Type in the desired DOS parameter using one line for each parameter.
4. Example: To permanently install “AMAX=NOREPEAT” and “ARCPRIO”

   <amax=norepeat>
   <arcprio>
   <Alt><f><s> to save the file
   <Alt><f><x> to exit MS-DOS Editor

   To view or edit the contents of the amax.ini file, follow the same procedure and either add new options or delete options. If no changes are made, exit editor with **<Alt><f><x>**. If changes are made, save changes with **<Alt><f><s>** prior to exiting with <Alt><f><x>.

   Note that there may be only one “AMAX=“ command active at any one time. If more than one is entered into the amax.ini file, only the last entered AMAX= command will be active. During booting, the amax.ini file is looked for after any DOS prompt entries. If the amax.ini file contains an AMAX= command and another is entered at the DOS prompt, the amax.ini command will be in effect when the operating program comes up.

Parameter	Description	C:\AMAX entry
DEMO	Operating program is entered ignoring the presence of the instrument. The status line will display DEMO in the bottom left corner. The same thing will happen any time the operating program is entered and the instrument is either not present or a signal is not received from the AML-BUS interface board.	<amax><space><demo> <Enter>
ITCHK	Incubation time check. In AMAX200 Status display, incubation times will be displayed in the sample ID area and the test being processed in the occupied positions of the incubation rail.	<amax><space><itchk> <Enter>
AUTOLAMP	The lamp is not turned on automatically with program initiation. The lamp is turned on only as needed (requested optical tests). The lamp will come on when processing is started on an optical test. After 15 minutes of inactivity, the lamp will turn off. This option may cause considerable wear and a shortening of the lamp life unless optical tests are only run on rare occasions.	<amax><space><autolamp> <Enter>

Parameter	Description	C:\AMAX entry
AMAX= USEPOOL	All sampling is from Reagent tray position #24. Useful for precision studies. Sample IDs may be entered in either QuickStart or Patients-New. In QuickStart, enter ID information into the first available space in an area that has as many empty spaces as the number of replicates you want to run. Order tests as usual. While holding down the <Shift> key, press the <↓> key to repeat with numerical increment for as many replicates as desired. In Patients-New, Enter ID in Ident.: area. Go to the test area and enter desired tests. Press <F5> to display the "Multiple Samples" screen and enter the number of replicates. Press <Esc> to finish. Start operation as usual. All sampling will be from position Reagent Tray position #24. Do not use this option while calibrating. To avoid lock-up of the instrument, all reagents (or water for those reagents that will not be used during usepool testing) for the selected Test Group must be present. Program must be exited when usepool testing is completed. Re-enter routine operating program with <a><Enter>.	<amax><space> <amax=usepool><Enter>
AMAX= TESTREAD	Not active. Dilution test. Absorbance readings are read before and after addition.	<amax><space> <amax=testread><Enter>
AMAX= NOREPEAT	Inhibits the auto-repeat function after CV or NC errors when testing in duplicate.	<amax><space> <amax=norepeat><Enter>
AMAX=TEST	Not active. As above in AMAX=TESTREAD plus the temperature is recorded. Information is dumped into temp.dmp file.	<amax><space> <amax=test><Enter>
AMAX= NONULBC	Disables the non\-readable barcode function. In normal startup, an empty position or an unreadable bar-code will be identified as "unknown n+" and the instrument will process it by running all tests in the test group; a single zero bar-code will be treated as an empty position with no tests processed; and, three zero bar-codes in a row will signal the end of processing. With the NONULBC option active: three empty or non-readable bar-codes in a row will stop processing; and, one empty position or an unreadable bar-code will be ignored with no tests processed and the instrument will proceed to the next sample.	<amax><space> <amax=nonulbc><Enter>
HOST=nn	<nn> defines the transmission retry time in seconds. Without this option, the timeout is 10 seconds.	<amax><Space> <host=transmission timeout retry time in seconds><Enter>

Parameter	Description	C:\AMAX entry
HOST=DUMP	All LIS communications (in and out) are dumped to a text file (hostdump.txt). Helpful when debugging LIS communication problems. Since a considerable amount of information is written to the file and only limited test editing tools are available, this option should be active for less than 1 hour.	<amax><space> <host=dump> <Enter>
HOST= NORESEND	Inhibits the repeated transmission of results after faulty attempts. Ensures that the host is not continuously busy because of host failures.	<amax><space> <host=noresend> <Enter>
LPT=HP	Enables a standard HP DeskJet printer driver	<amax><space> <lpt=hp><enter>
PCL=n	Allows switching of graphic drivers for HP DeskJet printers to a different PCL language level compatibility. Usual setting is “PCL=6” to switch to language level 6 compatibility. Without this option, the PCL language level is 3.	<amax><space> <pcl=language level><enter>
DUMP=n	Dumps to a text file (dmp.fle) every communication between the PC and the hardware module specified. Since a considerable amount of information is written to the file, this option should be active for less than 1 hour.	<amax.<space> <dump=hardware module number><Enter>
E=X2	Multiplies the absorbance values by 2 to compensate for the 0.5 mm lightpath. Not recommended as a routine operating parameter.	<amax><space><e=x2> <Enter>
NOBCCHK	Inhibits bar-code rescanning prior to start of each batch of samples. With the normal startup procedure, bar-codes are scanned initially and than are rescanned just prior to the start of sampling of that sample batch (batch size is set in Test Group definition).	<amax><space> <nobcchk><Enter>
STOPONQCERR	Enables automatic processing stop when a QC error occurs. The definition of the QC error that will activate the automatic stop is user definable with the Westgard rule setup. When this DOS option is active, automatic stop of all processing will occur if any enabled Westgard rule is violated.	<amax><space><stoponqcerr> <Enter>

Parameter	Description	C:\AMAX entry
NOREFILLTANK	Prevents monitoring of the level of fluids in the fresh water reservoir. During normal start-up the filling height of the fresh water container is checked. If refilling is required, a message is displayed requesting that the container be filled. The message will go away when the tank is refilled or when any key is pressed. The cooling tank levels are then checked. If either of these levels is low, a message will be displayed. After coolant has been added, the instrument and PC are turned off and restarted. With this option active only the cooling tanks are checked and only the low coolant message will be displayed. Instrument and PC must be restarted after corrective action is taken.	<amax><space> <norefilltank><Enter>
ARCPRIO	When operating in real-time mode, gives the patient archive request data priority over data received from the host.	<amax><space> <arcprio><Enter>
NOTANKCHECK	Every time the screen saver is activated, the cooling circulation levels are checked. When this DOS option is active, the additional monitoring of cooling circulation levels is disabled. This is intended to be used as a troubleshooting tool and should not be used on a routine basis.	<amax><space> <notankcheck><Enter>

12.5 Menus Outline

Type Legend: D = Display Only I = Operator Input
O = Operator Control Pr = Print Only
S = Set-up Parameters X = Service Engineers (Service password required)

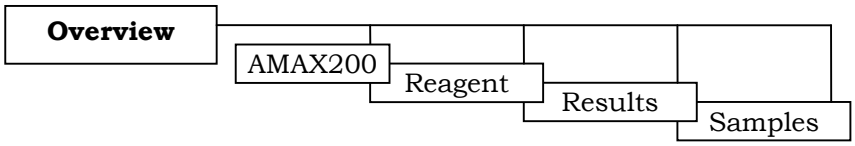
Main Menu	Topic Menu	Submenu	Security Level	Type	Description
Overview	AMAX200		0, 1, 2, 4	D	Displays current status of incubation rail, measuring wells, cuvette boxes and sample IDs being processed
	Reagent		0, 1, 2, 4	D	Displays positions of active reagent layout and reagent levels
	Results		0, 1, 2, 4	D	Displays results of current or last processing period
	Samples		0, 1, 2, 4	D	Displays processing status of request list
Service	Prime		0, 1, 2, 4	O	Primes pumps resulting in bubble-free filling of the syringe
	Wash		0, 1, 2, 4	O	Washes the probe in system fluid. May also be used to prime the system
	Transfer cup		0, 1, 2, 4	O	Transfers and discards one or more cuvettes out of the incubation rail
	Check Reagent		0, 1, 2, 4	O	Checks the levels on reagents for the selected test group reagent layout
	Lamp on/off		0, 1, 2, 4	O	Switches the lamp on or off according to current status
	Calibrate Photom.		Password or 4	X	Measures and displays photometer blank and dark current values
	Move syringe		0, 1, 2, 4	O	Moves syringe to a middle position to allow removal of syringe plunger
	Check volumes		0, 1, 2, 4	O	Dispenses any requested volume into a specified number of cuvettes
	Lock channels		0, 1, 2, 4	O	Allows deactivation of individual measuring channels
	Monitor		Password or 4	X	Displays communication information between PC and AMAX 200
Measure	Test Groups		0, 1, 2, 4	O	Selects test group for run
	Trays		0, 1, 2, 4	O	Opens Trays Submenu
		Show	0, 1, 2, 4	D	Displays current status of all sample trays
		Delete	0, 1, 2, 4	O	Deletes the position programming of a sample tray
Measure		Load	0, 1, 2, 4	O	Select tray for manual data entry
		Load auto	0, 1, 2, 4	O	Automatically load a sample tray

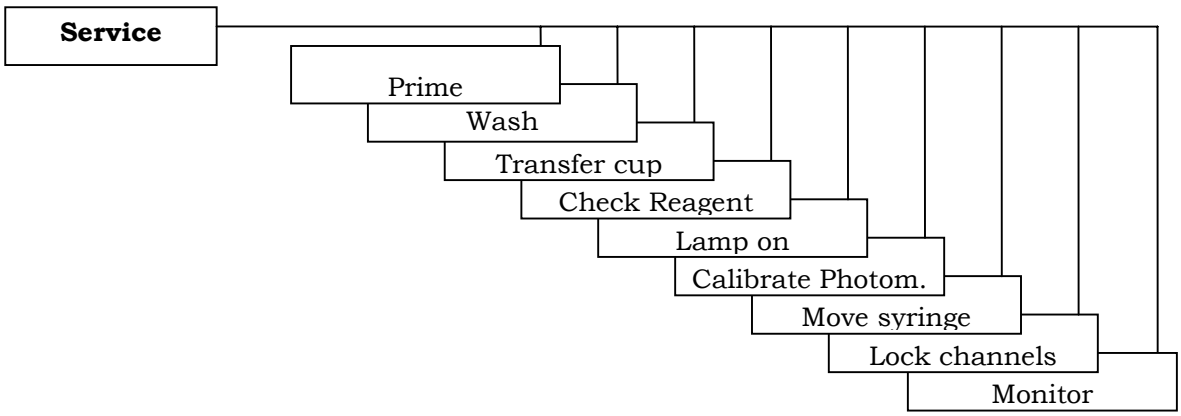
Main Menu	Topic Menu	Submenu	Security Level	Type	Description
	Robot right		0, 1, 2, 4	O	Moves the robot arm to the right to allow easier access to the reagent and sample trays
	Start		0, 1, 2, 4	O	Starts processing
	Graphic		0, 1, 2, 4	D	Real-time graphic display of optical test reaction
	Pause		0, 1, 2, 4	O	Halts processing for a controlled time period to allow loading of new samples, reagent refill, etc.
	Stop		0, 1, 2, 4	O	Stops sampling but completes tests in process (soft stop)
	Abort		0, 1, 2, 4	O	Stops sampling and processing with loss of all tests currently in process (hard stop)
Stat	Quick-Start		0, 1, 2, 4	O	Opens simplified one-screen user menu
	Positions 1 - 8		0, 1, 2, 4	I	Data entry for stat samples. Not displayed unless selected Test Group has assigned Stat positions
Patients	New		0, 1, 2, 4	I	New patient data entry
	Edit		0, 1, 2, 4	I	Correction or completion of patient data entries
	Add		0, 1, 2, 4	I	Addition to work list
	Repeat		0, 1, 2, 4	I	Deletes results to allow test repeat
	Import		0, 1, 2, 4	I	Patient data entry from L.I.S.-interface
	Export		0, 1, 2, 4	O	Transfer of results through L.I.S.-interface
	Patient list		0, 1, 2, 4	Pr	Prints patient list
	Result list		0, 1, 2, 4	Pr	Prints collated result list
	Result list on-line		0, 1, 2, 4	O	Transfers results through unidirectional interface
	Report		0, 1, 2, 4	Pr	Prints patient report
System	Format data files		0, 1, 2, 4	O	Deletes patient archive
System	Password or Sign ON or Set User PIN		Security OFF 0 1, 2, 4	O	With entry of password (security system not enabled) or PIN (security system enabled), opens following menus as appropriate to security clearance level.
	Drive		1, 2, 4	S	Selects disc drive and/or pathway for storing current patient archive
	Parameters		1, 2, 4	S	Opens following submenus

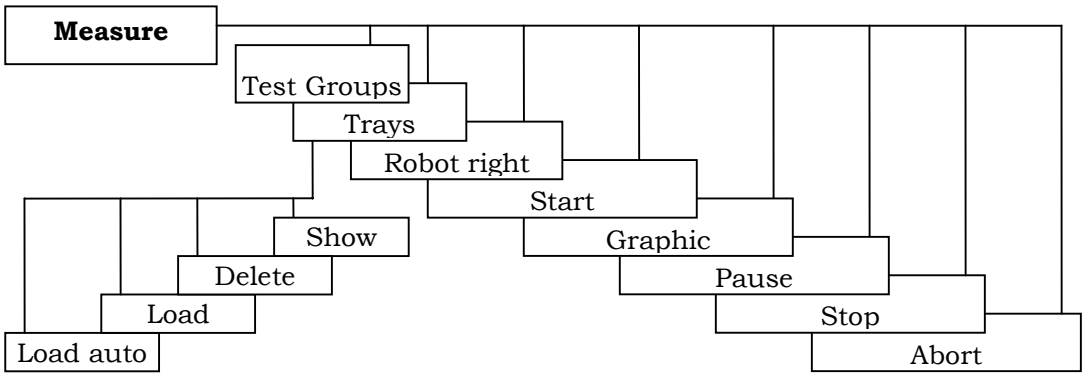
Main Menu	Topic Menu	Submenu	Security Level	Type	Description
		Test Groups	1, 2, 4	S	Defines up to 12 test groups containing up to 12 different tests
		Tests	1, 2, 4	S	Definition of test parameters
		Reagent Layout	1, 2, 4	S	Defines position of reagents in reagent tray
		Reagent	1, 2, 4	S	Reagent definition
		Levels	4	X	Definition of physical dimensions of reagent containers for accurate usage monitoring
		Pump	4	X	Syringe set-up parameters
		Meas. mode	1, 2, 4	S	Selection and assignment of measuring modes
		Temperature	4	X	Definition of temperature alarm limits
		Backup	1, 2, 4	O	Transfer of current parameters to a subdirectory on hard disc or to a floppy disc
		Restore	1, 2, 4	O	Downloads backup system set-up and/or test parameters to working directory
	Options		1, 2, 4	S	Processing and print options
	Host Par.		1, 2, 4	S	Definition of L.I.S.-interface parameters
	Location codes		1, 2, 4	S	Definition of location codes
	Panels		1, 2, 4	S	Definition of groups of tests as profiles
	Report format		1, 2, 4	S	Definition of patient report format
	Version		0, 1, 2, 4	D	Displays the current versions of the different modules and the PC software
Q.C.	Q.C. Charts		0, 1, 2, 4	I	
	Q.C. Files	Create	1, 2, 4	O	Open and close QC files
QC		List	0, 1, 2, 4	O	Display listing of all QC files stored on hard drive. Edit working Westgard Rules.
		Export	0, 1, 2, 4	O	Transfer data from QC files to a file ready to be exported to the Computrol[SM] QC program.
		Backup	0, 1, 2, 4	O	Archive QC data onto a floppy disc
		Restore	1, 2, 4	O	Restore previously backed up QC files to the hard drive QC File Directory
		Delete	1, 2, 4	O	Delete unnecessary QC files from hard drive

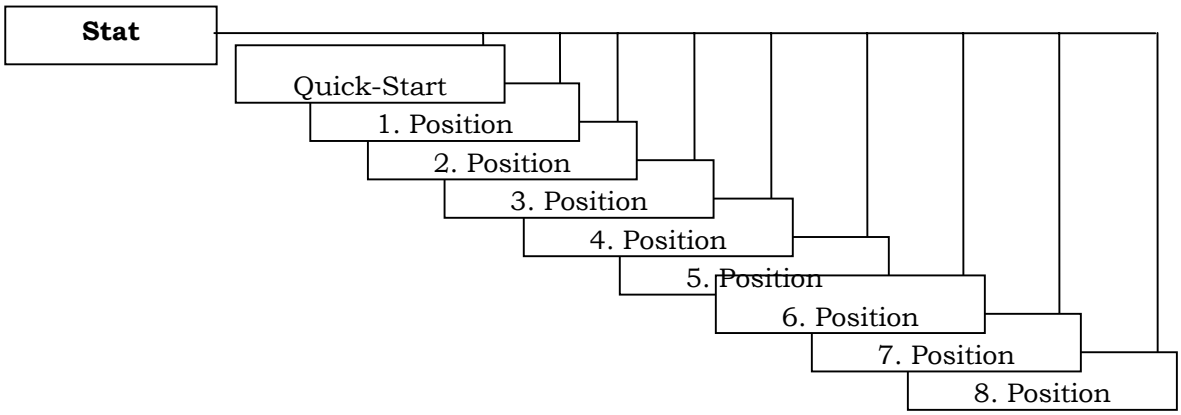
Main Menu	Topic Menu	Submenu	Security Level	Type	Description
	Q.C. Setup	Controls	1, 2, 4	S	Identify and define control evaluation limit criteria
		Westgard Defaults	1, 2, 4	S	Define default Westgard Rule setup
	Distribution		0, 1, 2, 4	D	Graphic display of sample result distribution
	Calib. curve		0, 1, 2, 4	D	Graphic display of selected standard curves
End	No		0, 1, 2, 4	O	Remain in AMAX operating program
	Yes		0, 1, 2, 4	O	Exit from AMAX operating program to DOS

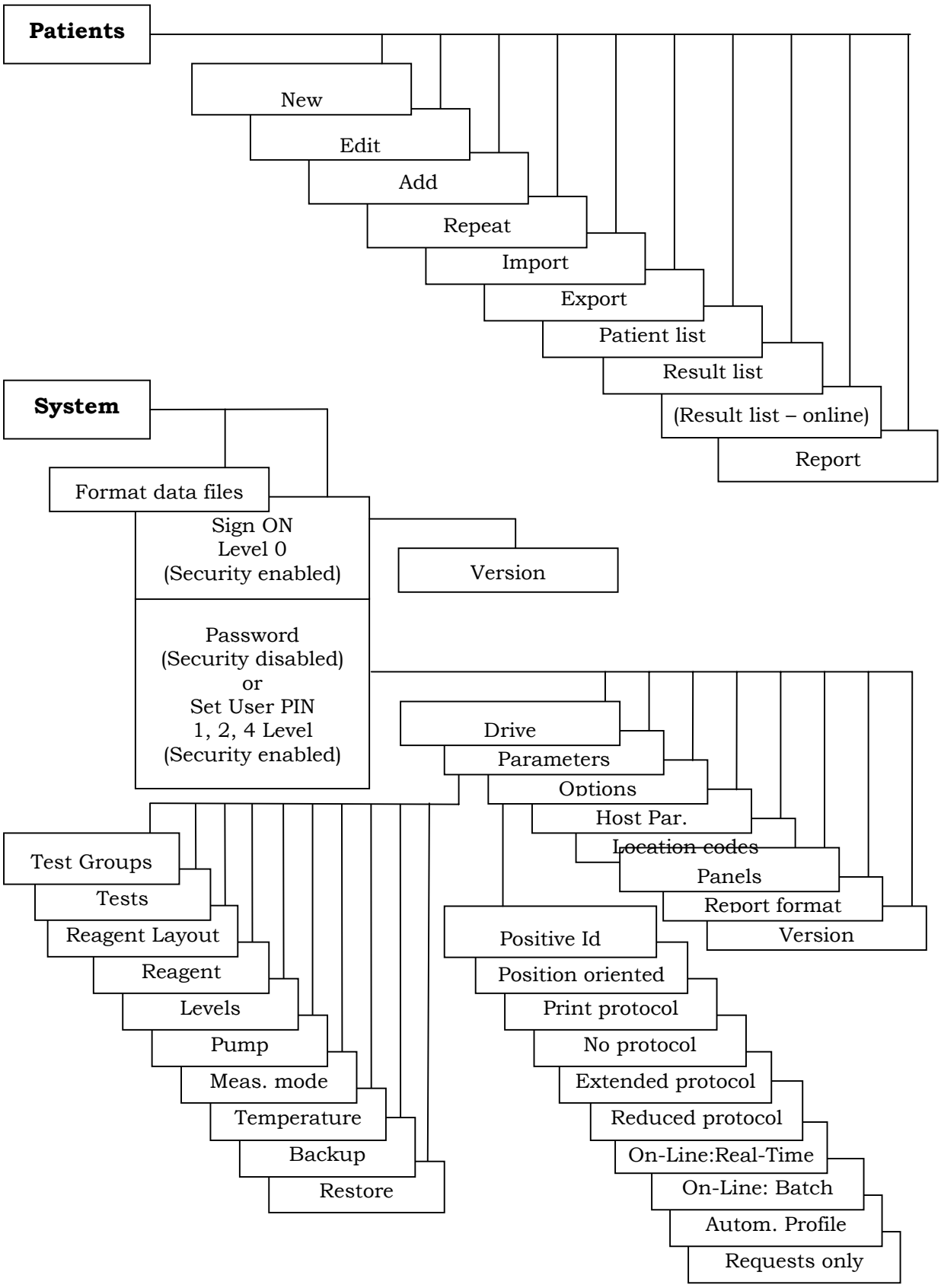
12.6 Menus Flowcharts

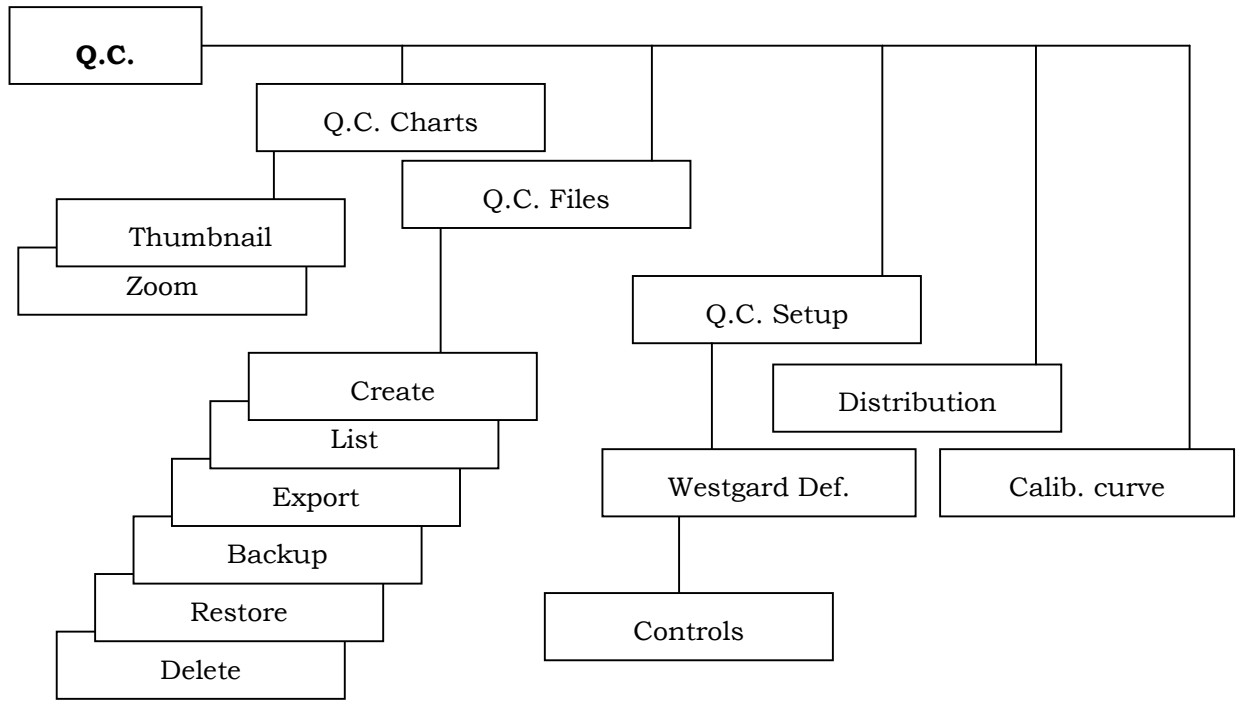


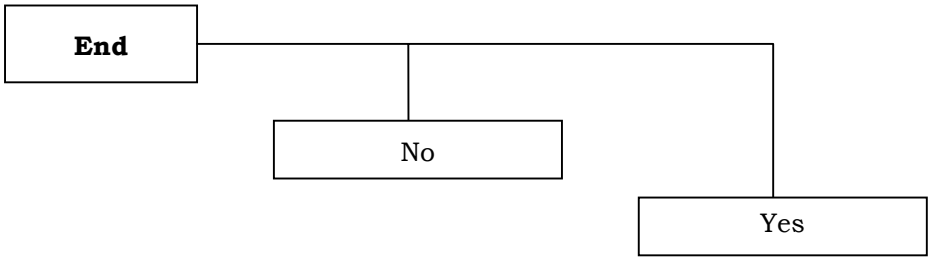







Patients
New
Edit
Add
Repeat
Import
Export
Patient list
Result list
(Result list – online)
Report
System
Format data files
Sign ON
Level 0
(Security enabled)
Version
Password
(Security disabled)
or
Set User PIN
1, 2, 4 Level
(Security enabled)
Drive
Parameters
Options
Host Par.
Location codes
Panels
Report format
Version
Test Groups
Tests
Reagent Layout
Reagent
Levels
Pump
Meas. mode
Temperature
Backup
Restore
Positive Id
Position oriented
Print protocol
No protocol
Extended protocol
Reduced protocol
On-Line:Real-Time
On-Line: Batch
Autom. Profile
Requests only


Q.C.
Q.C. Charts
Q.C. Files
Thumbnail
Zoom
Q.C. Setup
Create
List
Export
Backup
Restore
Delete
Distribution
Westgard Def.
Calib. curve
Controls


End
No
Yes

13 OVERVIEW MENU 13-1
13.1 AMAX 200 13-1
13.2 REAGENT 13-2
13.3 RESULTS 13-3
13.4 SAMPLES 13-4

Overview Menu

The Overview menu contains options that provide real-time oversight of what is happening while samples are being processed.

The different processes that can be observed are:

1. Total operation overview
2. Reagent usage levels
3. Review results as they are processed
4. Check the stage of processing for each sample

Open the Overview window by either pressing **<o>** or moving the cursor to Overview and pressing **<Enter>**.

[Overview]

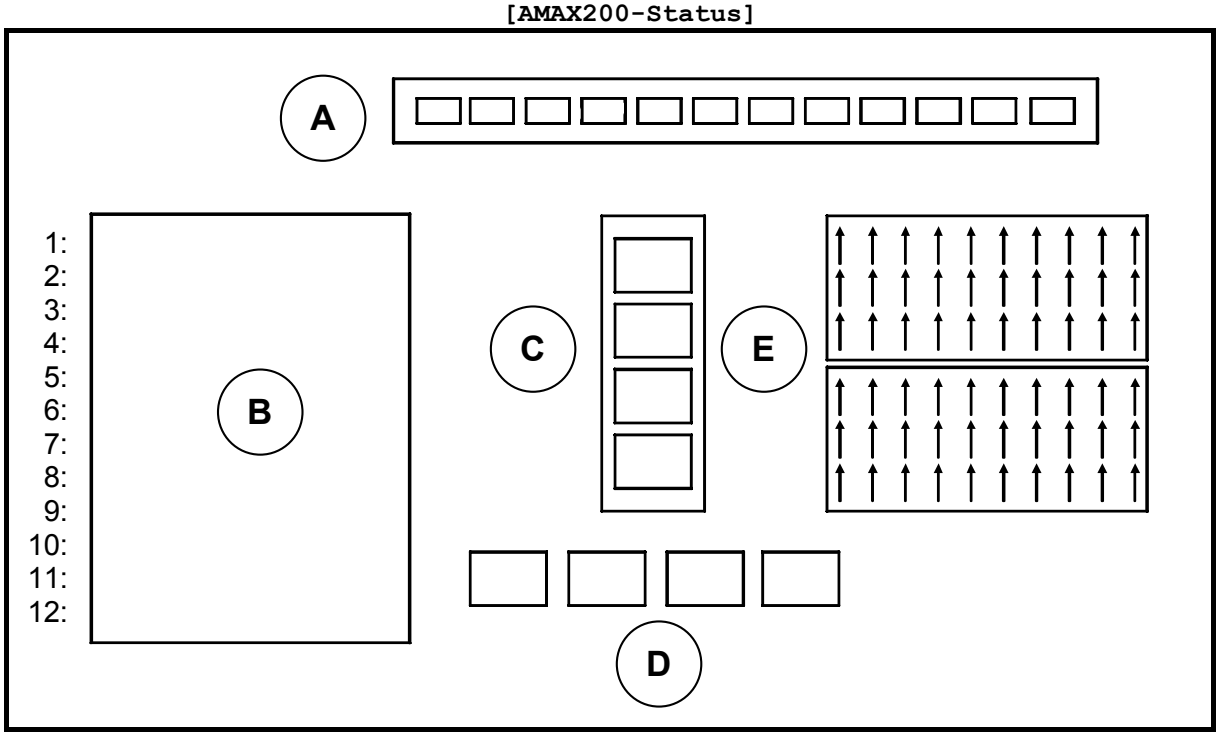
AMAX200	Section 13.1
Reagent	Section 13.2
Results	Section 13.3
Samples	Section 13.4

13.1 AMAX 200

Password security system: unrestricted
PIN security system: 2, 1 and 0 = unrestricted

With the "Overview" menu open, press **<c>** or move the cursor to **"AMAX 200"** and press **<Enter>.** The "AMAX 200 - Status" window opens. This is a display only window. It provides the opportunity to observe just what is going on.

[AMAX200-Status]



Key	Description
A	12-position incubation rail area. Incubation area for samples in process prior to addition of starting reagent. RED = position contains a sample in process GREEN = open incubation position
B	Sample identification area. Contains a listing of the sample batch currently being processed. See Chapter 12, Section 12.4, DOS parameter “ITCHK” for an alternative display.
C	Optical measuring wells RED = measurement in process. Real-time graphic reaction representation can be obtained (graphics mode ON). GREEN = open measuring position BLACK = position has been locked and will not be used for measurement
D	Mechanical measuring wells. RED = measurement in process. GREEN = open measuring position BLACK = position has been locked and will not be used for measurement
E	Cuvette box area. GREEN = box present RED = box missing. Run will be aborted if not replaced.

13.2 Reagent

Password security system: unrestricted
PIN security system: 2, 1 and 0 = unrestricted

Having an adequate supply of reagent available for testing is an essential prerequisite to testing. The “Reagent” window provides a means to tell at a glance what reagents are required, where they are to be positioned and whether or not any reagents need replenishment.

With the “Overview” menu open, press **<g>** or move the cursor to **“Reagent”** and press **<Enter>.** The “Reagent Overview” window opens.

[Reagent overview]

Cleaner

	1. Ring (outer)		2. Ring (middle)		3. Ring (inner)
1	Stat	9	ThromboMAX	17	
2	Stat	10		18	APTT
3	Stat	11		19	Calcium Chloride
4	Stat	12		20	
5	Stat	13		21	Thrombin (FIB)
6	Stat	14		22	
7	Stat	15	Imidazole Buffer	23	AT Thrombin/Heparin
8	Stat	16		24	AT Substrate

The exact position in the reagent tray of all reagents required for processing a group of tests is displayed. Stat sampling is from the reagent tray not the sample tray. Positions 1 through 8 in any given reagent layout can be used for either reagents or as Stat sample positions. The reagent overview window shows the availability of Stat positions. During processing, the reagent level is measured every time the probe goes to aspirate reagent. The "Reagent Overview" window will be constantly updated and always represents the actual level of each reagent. The accuracy of level monitoring is dependent on having accurately defined reagent containers. Reagent levels are discussed in Section 19.5 – System, Parameters, Levels.

19.5

The last measured level of each reagent is indicated by the green bar. The red bar indicates the amount of reagent that has been used. If the red bar is flashing, the reagent is below the minimum level required prior to processing. The minimum level required is defined for each reagent. Reagent definition is discussed in Section 19.4 – System, Parameters, Reagent.

19.4

Stat positions that are in use are highlighted in red.

If the Test Group has been changed or if no processing has been performed using this reagent layout, all levels will be indicated in red regardless of the actual amount of reagent present.

If a new Test Group has been selected or if this is the first processing period using this Test Group, the first thing that the instrument does when processing starts is to check reagent levels. The "Reagent Overview" display will be updated as each reagent level is checked. Anytime the instrument is not processing, the reagent levels can be checked and updated automatically. This will be discussed in Section 14.4 – Service, Check reagent.

14.4

13.3 Results

Password security system: unrestricted
PIN security system: 2, 1 and 0 = unrestricted

The "Results" window displays real-time results or, if processing has ended, the results of the last processing period.

With the "Overview" menu open, press **<r>** or move the cursor to "Results" and press **<Enter>**. The "Results" overview window will open.

[Results]

↓, ↑, Home, End: forward, back, Home, End

Pos	ID code	Test		Val.1	Val.2	Result
1	101			Mazie Cornflake		
		PT-M	:	14.3		14.3
		PTT-O	:	35.8		35.8
		AT	:	734.8	729.5	60%, 732.2 mE
2	102			Rodney Rutabaga		
		FIB	:	wait		

Column	Description
Pos	Sample tray position of the sample
ID code	Identification code of the sample.
Test	Test Code for requested test
Val. 1	First measured value (time or mE) for duplicate or single sampling. “Wait”, if test not completed. Error message if testing completed but no result obtained
Val. 2	Second measured value (time or mE) for duplicate sampling
Result	Result in reporting units defined in Test Parameters/Data reduction

Move up and down using the **<arrow>**, **<Home>**, and **<End>** keys.
The listing is sample tray position related. The name given to the sample is displayed above the two value columns.
Press **<Esc>** to close the “Results” window.

13.4 Samples

Password security system: unrestricted
PIN security system: 2, 1 and 0 = unrestricted

The “Samples” overview window displays the processing status of all samples assigned to a specified sample tray.
With the “Overview” window open, press **<s>** or move the cursor to **“Samples”** and press **<Enter>**. The “Samples” window will open.

[Samples]

```
  .:OK                      P  F  P  F  F  A  H
  *:Not processed    P  R   T  1  T  9  I  T  E
  E:Error            o      O  B  T     B     P
  e:Empty            s  #      M  O
101 Jiminy Cricket   1  1            .     *  *  *
102 _______________  2  1   .  .
103 Mark Twain       3  1   E  .  .  .  *  *
104 Samuel Clemens   4  1   .     .
105 Tom Troglodyte   5  1   .  .  e  e  e  e
```

Key	Description
Upper left-hand corner	Definitions of codes used in test columns
Sample ID and Name	Unique ID and name (if any) given to sample
Pos	Sample tray position
R #	Sample tray
Test codes	First 4 characters in test code
Status codes	Show the processing status for each test for each sample * = test ordered, pending processing, text after asterisk is the message entered for Error Code 0. . = testing completed, results OK E = error occurred during testing, no result e = no sample present, no result

The processing status of any programmed sample can be viewed. The “Samples” overview window is dynamic and updates continually during processing.

14 SERVICE MENU 14-1
14.1 PRIME 14-1
14.2 WASH 14-2
14.3 TRANSFER CUP 14-2
14.4 CHECK REAGENT 14-3
14.5 LAMP OFF/ON 14-3
14.6 CALIBRATE PHOTOMETER 14-4
14.7 MOVE SYRINGE 14-4
14.8 CHECK VOLUMES 14-4
14.9 LOCK CHANNELS 14-4
14.10 MONITOR 14-6

The Service menu contains options for doing several utility tasks. All utility tasks are done when the instrument is not processing and the status is “Ready”. If the instrument is asked to do these tasks when the status is “Busy”, an audible alert will sound and an error message will be displayed.

Error
AMAX 200 is busy!

To turn the alarm off, press **<Alt-F2>**.

Open the “Service” menu by either pressing **<s>** or moving the cursor to Service and pressing **<Enter>**.

Prime	Section 14.1
Wash	Section 14.2
Transfer cup	Section 14.3
Check Reagent	Section 14.4
Lamp off/on	Section 14.5
Calibrate Photom.	Section 14.6
Move syringe	Section 14.7
Check volumes	Section 14.8
Lock channels	Section 14.9
Monitor	Section 14.10

14.1 Prime

Password security system = unrestricted
PIN security system = unrestricted

Optimum performance of the AMAX 200 is dependent on having a bubble free hydraulic system. Part of the daily maintenance checks includes a visual examination of the tubing lines for air bubbles. Prime should be done anytime bubbles or air gaps are observed in the tubing leading to and from the syringe. It should always be done after adding a fresh supply of water or after the removal of the suction tube/sensor assembly from the fresh water container. Prime should always be done after syringe cleaning or replacement.

With the “Service” menu open, press **<p>** or move the cursor to **“Prime”** and press **<Enter>**.

A prime cycle will start. The probe goes down into the rinse well. The syringe goes fully down and back up twice followed by 5 fast down and up cycles. During the fast syringe cycles, water will be aspirated into the syringe and dispensed out through the probe. Approximately 2 ml of water is pumped through the lines during a prime cycle. Observe the lines leading to and from the syringe. If bubbles are observed, flick the tubing during the fast cycles to move the bubbles into the syringe so that they will be pumped out through the line during the priming process. Repeat if large bubbles or air gaps persist. A few small bubbles are not a cause for alarm although their presence may suggest that the syringe needs to be cleaned or replaced.

14.2 Wash

Password security system = unrestricted
PIN security system = unrestricted

Optimum test performance is dependent on having an uncontaminated sample and reagent transfer system. The AMAX 200 automatically rinses itself with water every 5 minutes whenever the system is active. The "Wash" task is initiated whenever additional washing with cleaner is considered necessary. Multiple wash cycles may be requested.

Wash should be done before shutdown whenever the instrument will be out of service for more than one day.

With the "Service" menu open, press **<w>** or move the cursor to **"Wash"** and press **<Enter> <Enter>**. When <Enter> is pressed twice, a window opens which allows entry of the desired number of wash cycles to be done.

```
Number of cycles: # (flashing)
```

The number of wash cycles last requested (usually 1) is displayed and may be changed to any number between **<1>** and **<20>**. Type in **<wanted # of cycles>** followed by **<Enter>**. The default number for wash cycles is one.

To initiate a system wash without changing the previously programmed number of cycles, move the cursor to **"Wash"** and press **<Enter>** once. The probe goes down into the rinse well; then it goes up and over to the Enzyclean station and aspirates 200 µl Enzyclean; and finally it moves back to the rinse station where approximately 8 ml of water is pumped through the probe to complete the cleaning process.

WARNING!
Bleach or other harsh chemical cleaners will cause damage to the probe and should not be used.

14.3 Transfer Cup

Password security system = unrestricted
PIN security system = unrestricted

The "Transfer cup" command moves a specified number of cuvettes out of the incubation rail and over to one of the optical measuring wells for disposal. The most common reason for doing this is to check the function of the cuvette transfer system.

With the "Service" menu open, press **<t>** or move the cursor to **"Transfer cup"** and press **<Enter><Enter>**. When <Enter> is pressed twice, a window opens which allows entry of the desired number of cuvettes to be transferred. The transfer of any number between **<1>** and **<400>** may be requested. Transfer will automatically stop when one box remains.

```
Number of cuvettes:_ _ _
```

Type in the **<number of cuvettes>** followed by **<Enter>**. Cuvette transfer will begin and continue until the requested number of cuvettes has been transferred.

14.4 Check Reagent

Password security system = unrestricted
PIN security system = unrestricted

The AMAX 200 monitors the level of all reagents being used during processing. Under these circumstances, the reagent usage monitor is constantly updated. If reagent is replenished when the instrument is not processing, the reagent usage monitor may be updated by doing the "Check Reagent" task.

WARNING!
Assure that the lids of all reagents assigned in reagent layout for the active test group are off.

With the "Service" menu open, press **<c>** or move the cursor to **"Check Reagent"** and press **<Enter>**.

The probe will go to each reagent assigned in the reagent layout for the active Test Group and check the reagent level. If the cleaner level is below the defined minimum level, no other levels will be checked. The reagent usage monitor will be updated and may be viewed in Reagent Overview (Section 13.2, Overview, Reagent).

13.2

14.5 Lamp Off/On

Password security system = unrestricted
PIN security system = unrestricted

The life of the photometer lamp may be extended if the lamp is turned off anytime the instrument is active but will not be processing optical tests for periods exceeding 24 hours.

When the "Service" menu is open, "off" or "on" will be displayed according to which option is not currently selected. If the lamp is on, the selection will be "off". If the lamp is off, the selection will be "on". Whenever the lamp is off, the lamp status area at the bottom of the main menu screen will be red and the front panel status light will be red.

To change the lamp status: With the "Service" menu open, press **<l>** or move the cursor to **"Lamp on/off"** and press **<Enter>**.

When changing the lamp status from "off" to "on", it will take approximately 1 minute for the status to change to "on". To reduce stress on the lamp, the voltage to the lamp is brought up slowly. The status indicator will say "wait". Once the lamp is fully powered, the screen lamp status will no longer be red and the red front-panel status light will no longer be lit.

14.6 Calibrate Photometer

Password security system = Service password
PIN security system = 2, 1 and 0 restricted; 4 access

This task is used to measure the photometer blank, dark current and air values of the optical measuring wells. This is not a routine operating task. Because the function of the photometer is critical to the instrument performance, this area is protected by a service password. Photometer calibration is covered in Section 23.5.1. Photometer calibration may be suggested when troubleshooting optical channel performance. Note that no photometer adjustments are done during this procedure. It is a measure and display only function.

23.5.1

14.7 Move Syringe

Password security system = unrestricted
PIN security system = unrestricted

This task is used to move the syringe plunger down to a position from which it may be removed for cleaning or replacement. This is not a routine operating task.

Cleaning of the syringe is done as part of the monthly maintenance and is covered in Section 23.4.1.

23.4.1

14.8 Check Volumes

Password security system = unrestricted
PIN security system = unrestricted

This task is used to check the accuracy of specified aspiration/dispense volumes. This is not a routine operating task. Volume checking may be suggested when trouble-shooting excessive variance observed in both optical and mechanical channels. Checking volumes is a maintenance procedure and is covered in Section 23.5.2.

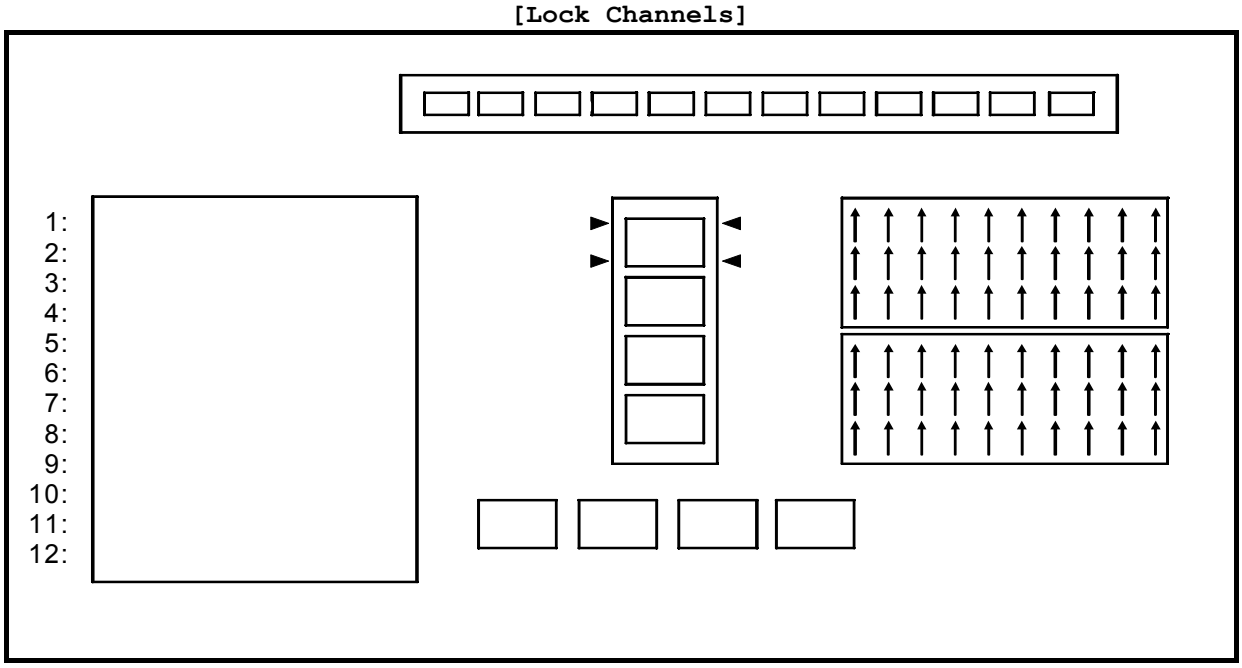
23.5.2

14.9 Lock Channels

Password security system = unrestricted
PIN security system = unrestricted

This task is used to exclude individual measuring channels from use. Channel locking is used during troubleshooting to identify measuring channel malfunctions. Once the malfunctioning channel has been identified, it may be removed from active use. This allows continued use of the instrument even in the event of measuring channel failure.

With the "Service" menu open, move the cursor to **"Lock channels"** and press **<Enter>**. The "Lock channels" window will be displayed.



The "Lock channels" window looks like the "AMAX200-Status" screen except that it has 4 bright red triangles that bracket a measuring channel.

1. Channel locking: Use the **<arrow>** keys to move the cursor to the channel that is to be "locked" (removed from active use). Once the red arrowheads are bracketing the desired channel, press **<Enter>**. The channel color changes from green to black indicating that the channel has been removed from active use.
2. As many channels may be locked out of service as desired. Testing using the remaining channels may still be performed if no more than three channels of a type are locked out. If all optical or all mechanical channels are locked, no testing of that type may be done. If all channels of a type are locked out, as soon as the "Lock channels" screen is exited, the message "Change of configuration! Terminate program and restart" will be displayed. Exit Operating Program to effect the lockout. **<End><Yes>**. Re-enter the program by typing **<a><Enter>** at the c:\AMAX> prompt.

   If a Test Group is selected that contains tests defined for the locked out channels is selected, the message "ERROR Measuring channels not configured" will be displayed. If the Procedure section of a Test defined using the locked out channels is accessed, a small "x" will be displayed in the "Meas. m." field. The measuring mode(s) usually listed for the locked-out type will not be available as options and will not be listed when <F1> is pressed.
3. **Channel unlocking**: The procedure for unlocking channels is the same. Use the **<arrow>** keys to move the cursor to the channel that is to be "unlocked" (returned to active use). Once the arrowheads are bracketing the desired black channel, press **<Enter>**. The channel color changes from black to green indicating that the channel is now available for active use. If all channels of a type were previously locked out, when any of the channels are unlocked, the message "Change of configuration! Terminate program and restart" will be displayed. Exit the Operating

Program by pressing **<End><Yes>**. Re-enter the program by typing **<a><Enter>** at the c:\AMAX> prompt.

14.10 Monitor

Password security system = Service password
PIN security system = 2, 1 and 0 restricted; 4 access

If the PIN security system is enabled, the monitor submenu does not display as a submenu of the Service Menu except after entry of a Level 4 PIN. If the PIN security system is not enabled, the monitor submenu section is protected by the service password.

The monitor function displays communication information between the PC and the AMAX 200. It is of no interest to the routine operator.

15 MEASURE MENU.....15-1
15.1 TEST GROUPS..... 15-1
15.2 TRAYS..... 15-2
15.2.1 Show..... 15-4
15.2.2 Delete..... 15-4
15.2.3 Load..... 15-5
15.2.4 Load Auto..... 15-6
15.3 ROBOT RIGHT..... 15-6
15.4 START..... 15-6
15.5 GRAPHIC..... 15-12
15.6 PAUSE, STOP AND ABORT..... 15-14
15.6.1 Pause..... 15-14
15.6.2 Stop..... 15-15
15.6.3 Abort..... 15-15

Measure Menu

The Measure menu contains tasks used when starting and interrupting the measuring process.

Open the “Measure” menu by pressing **<m>** or by moving the cursor to **“Measure”** and pressing **<Enter>**.

[Measure]

Test Groups	Section 15.1
Trays	Section 15.2
Robot right	Section 15.3
Start	Section 15.4
Graphic	Section 15.5
(Pause)	Section 15.6
(Stop)	Section 15.6
(Abort)	Section 15.6

Tasks that are unavailable either for operation status or for security reasons are displayed in gray. For example: In the “Measure” menu, “Pause, Stop and Abort” will be displayed in gray anytime the instrument is not processing. Once processing starts, “Pause, Stop and Abort” are valid tasks and will be displayed in black indicating that these tasks are available.

15.1 Test Groups

Password security system = unrestricted
PIN security system = unrestricted

Up to 32 tests may be programmed on the AMAX 200. Up to 12 of these 32 tests may be performed simultaneously. Since not all 32 tests can be run at the same time, tests are organized into groups containing from 1 to 12 tests. There are no restrictions as to which tests may go into a group. Up to 12 “Test Groups” may be defined. Any programmed test may be a part of one or more Test Groups. All processing on the AMAX 200 is done using Test Groups. Confirmation of the Test Group selection is required before the start of processing. Programming of Test Groups is covered in Section 19.1, System, Parameters, Test groups.

19.1

The currently selected Test Group is always displayed in the lower right-hand corner of the Main menu status bar. If no group has been selected, the area above the file format date is empty.

With the “Measure” menu open, either press **<t>** or move the cursor to **<Test groups>** and press **<Enter>**. The “Test groups” window will open.

[Test groups]

Group
PT
PTT
PT/PTT
FIB
PT/PTT/FIB
AT3
F8/F9
Quick Start

Move the cursor to the desired “**Test Group**” and press **<Enter>**. The main menu status bar updates and the selected group is displayed as the currently active Test Group.

15.2 Trays

Password security system = unrestricted
PIN security system = unrestricted

The AMAX 200 has a 60-position sample tray. Up to 60 samples may be programmed into specific sample tray positions. Up to 17 sample trays (1020 samples) may be programmed.

The “Trays” option is active only when samples are being programmed manually and only when the instrument is not processing. When barcodes are being used and Positive-Id is active, this menu and related submenus are not available.

With the “Measure” menu open, either press **<y>** or move the cursor to **“Trays”** and press **<Enter>**. The Trays submenu will open.

[Trays]

Show
Delete
Load
Load auto

The Trays submenu is used to monitor and manipulate contents of the sample trays.

Option	Function Summary (see below for comprehensive discussion)
Show	Lists the beginning and ending sample ID codes. Selecting one of the listed trays brings up a complete listing for that tray
Delete	Deletes the load map for a specifically selected tray. Only the load map is deleted. The demographic information and any results for samples previously programmed are not deleted from the patient archive
Load	Allows editing of the load map for a selected tray. Also allows moving of samples from one tray to another
Load auto	Automatically loads an empty tray with unprocessed sample ID codes in the patient archive

Whenever any of the Tray submenus (Show, Delete, Load, Load auto) are opened the "Select tray" dialog window opens.

[Select tray]

No	No smp	first ID	last ID	Status
1	25	101	125	loaded
2	31	201	231	ready
3	6	301	306	ready
4	25	401	425	ready
5	5	501	505	ready
6	0			free
.	0			free
.	0			free
17	0			free

Index	Description
No	Sample tray number
No smp	The number of samples already positioned on the tray
first ID	The sample ID of the first sample on the tray
last ID	The sample ID of the last sample on the tray
Status	The status of the tray free = no samples programmed ready = inclusive sequential samples have been processed loaded = tray is loaded and set for processing in use = tray is in process; access will be denied, only seen when in the <Patients><New> or <Edit> screens finished = tray is full and processed not comple = tray has empty non-sequential positions

15.2.1 Show

To access the "Show" options, press **<s>** or move the cursor to **"Show"** and press **<Enter>**. The "Select tray" dialog window will appear.

To select a tray for a comprehensive listing of all sample IDs positioned on the tray, move the cursor to the **<desired tray>** and press **<Enter>**.

[Select Tray]

Tray (selected tray #)		
1: 301	21:	41:
2: 302	22:	42:
3: 303	23:	43:
4: 304	24:	44:
5: 305	25:	45:
6: 306	26:	46:
7:	27:	47:
8:	28:	48:
9:	29:	49:
10:	30:	50:
11:	31:	51:
12:	32:	52:
13:	33:	53:
14:	34:	54:
15:	35:	55:
16:	36:	56:
17:	37:	57:
18:	38:	58:
19:	39:	59:
20:	40:	60:

The exact location of any sample ID programmed on the selected sample tray may be determined.

Press **<any key>** to close the window.

15.2.2 Delete

Sample trays may be deleted which enables the reuse of that sample tray for additional samples. Sample demographics and results are not deleted. Demographics and results are still stored in the patient archive.

To access the "Delete" options, press **<d>** or move the cursor to **"Delete"** and press **<Enter>**.

The "Select tray" dialog window opens. To select a tray for deletion, move the cursor to the **<desired tray>** and press **<Enter>**.

If the status of the tray is anything except "ready", a warning message will be displayed:

```
Sample tray (#) not processed !
Delete ?  NO
```

If you do want to delete the tray even though all samples have not been processed, confirm deletion with **<y> <Enter>**.

If you decide not to delete the tray, press **<Enter>**.

15.2.3 Load

The load map for any sample tray may be modified using the "Load" option. Additional samples may be added; samples may be removed; and samples may be moved from one tray to another.

To access the "Load" options press **<l>** or move the cursor to **"Load"** and press **<Enter>**.

The "Select tray" dialog window opens. To select a tray to load, move the cursor to the **<desired tray>** and press **<Enter>**. The "Trays load" dialog window is displayed.

[Trays (selected tray #) Load]

1: 301	17:	33:
2: 302	18:	34:
3: 303	19:	35:
4: 304	20:	36:
5: 305	21:	37:
6: 306	22:	38:
7:	23:	39:
8:	24:	40:
9:	25:	41:
10:	26:	42:
11:	27:	43:
12:	28:	44:
13:	29:	45:
14:	30:	46:
15:	31:	47:
16:	32:	48:

To add a sample: Move the cursor to an empty position. Type in a registered **"sample ID"** followed by **<Enter>**. ID must already be in the patient archive.

To remove a sample: Move the cursor to the sample to be removed. Press **<Space>** **<Enter>**.

ATTENTION!
Sample removed will not be assigned to any sample tray. It may be manually assigned to another tray by selecting that tray to load or automatically through the "load auto" option.

To move a sample from another tray to the selected tray or from one position to another position on the same tray: Move the cursor to an empty position. Type in the "sample ID of the sample to be moved" to this tray followed by <Enter>. A caution message is displayed:

[Caution]

```
Sample from pos. (position # / tray #) moved
```

Press **<any key>** to clear the message.

If a large number of samples need to be moved from one tray to another, rather than responding repeatedly to this message, it is easier and quicker to remove them from the first tray and then add them to another tray using either "load" or "load auto".

15.2.4 Load Auto

This option is used to automatically load a sample tray with any samples in the patient archive that have unprocessed tests.

To access the "Load auto" option, press **<a>** or move the cursor to **"Load auto"** and press **<Enter>**. The "Select tray" dialog window is displayed.

Move the cursor to a "free" tray and press **<Enter>**.

The patient archive is searched for any unprocessed tests and automatically loads the selected sample tray. Samples are positioned in the tray in the archive sequence.

After the automatic tray loading, the load map is displayed. Use the load map to position samples in the sample tray. The load map may be printed by pressing **<Print Scrn>**. Press **<any key>** to close the dialog window.

ATTENTION!
Check positioning carefully. Samples are assigned according to their position in the patient archive not by sample ID sequence.

15.3 Robot Right

Password security system = unrestricted
PIN security system = unrestricted

The "Robot right" option is available any time the instrument is not processing.

The "Robot right" option is used to facilitate addition and removal of either samples or reagents to and from the storage area. The normal position of the robot when not processing is over the rinse well. This positioning restricts access to the sample/reagent trays storage area. Moving the robot to the right allows easier access to the storage area. With the "Measure" menu open, press **<r>** or move the cursor to **"Robot right"** and press **<Enter>**.

The robot moves right to a position to the right of the last optical measuring well. The sample and reagent trays may be easily removed. Routine samples, Stat samples and reagents may also be added without removing the trays.

"Robot right" is not available once processing has started. The robot will automatically move right during the "Pause" function. See section 15.6.

15.4 Start

Password security system = unrestricted
PIN security system = unrestricted

Processing may begin any time after samples have been programmed; or, if positive Id and auto-profile are on, after samples have been placed in the sample tray. The "Start" command is used to initiate processing. Before starting processing, the following conditions should be checked:

- All stoppers have been removed from sample tubes;

- All lids have been removed from reagent containers that will be accessed during the processing period;
- The cover of the reagent/sample tray storage area is on;
- The cuvette waste bin is not full and that the drawer is closed;
- The cuvette box disposal area is not full;
- The supply of fresh water is adequate;
- The waste water container is not full;
- The supply of Enzyclean is adequate; and
- No objects are on the working surface of the instrument or under the diluter syringe.

To start processing: With the "Measure" menu open, press **<s>** or move the cursor to **"Start"** and press **<Enter>**.

When the "Start" command is given, the AMAX 200 does internal checks to ascertain that all working conditions are within specifications. The instrument verifies that: all temperatures are within the specified ranges; the fresh water reservoir is not empty; the drain container is not full; at least two cuvette boxes are in the chute; and, the lamp is on.

If one or more of the conditions are not met, the AMAX200-Status window is displayed.

[AMAX200-Status]

Temperature	Sample/Reagent	16.2	Any condition out of specification will be displayed in a red field.
	Probe	35.3	Wait for temperatures. It will take approximately 20–30 minutes for all modules to reach operating temperature after power ON.
	Opt. Meas.	37.0	
	Mech. Meas.	36.7	
	Incubation	36.0	
	Cooling	35.2	
Photom. lamp	Status	on	Change lamp status to "on" <Service><Lamp on><Enter>
	condition	OK	
Sys. fluid	Input	OK	Add fresh water.
	Output	OK	Empty drain container.
	Wash cycles	0/0	Wait for wash cycles to end.
Cuvettes	Input	OK	Insert at least 2 cuvette boxes.
	Tray waste	OK	Empty cuvette waste chute.

When all error conditions have been corrected, press **<Esc>** to exit the AMAX200-Status window.

Restart processing: Open the "Measure" menu and press **<s>** or move the cursor to **"Start"** and press **<Enter>**.

When there are no error conditions, the “Start-Test group” dialog window is displayed.

```
          [Start - Test group]
F1:Reagent Layout  F2:Sample Overview

Name      : Routine
Group     : 4
Reagent   : ROUTINE

       Tests -- Replicates
   1: PT           Single
   2: PTT          Single
   3: FIB          Duplicate
   4:
   5:
   6:
   7:
   8:
   9:
   10:
   11:
   12:
  Confirm  : YES
```

Name of currently active Test Group
Sample batch size
Reagent layout assigned to Test Group

First test in group; single sampling
Second test in group; single sampling
Third test in group; duplicate testing

Request for confirmation that this is the correct Test Group to use.

All testing on the AMAX 200 is done in “Test groups”. The currently active Test Group is always displayed in the status bar in the lower right-hand corner of the Main Menu.

Confirmation of the Test Group is always required before the actual start of processing. It is more efficient to preselect the Test Group before issuing the “Start” command.

The options for answering the confirmation request are:

1. If the correct Test Group is selected, press **<Enter>**.

   Function keys <F1:Reagent Layout> and <F2:Sample Overview> may be used to assist in determining if the Test Group selected is the correct one to use for the tests to be run. Pressing <F1> will show what reagents are associated with the selected Test Group. Pressing <F2> will show the “Sample-Status” screen. Samples marked with an asterisk (*) in any test columns have pending tests.

2. If the Test Group is not the one you want to use, deny the confirmation by pressing **<n><Enter>**.

   The start procedure is terminated. Open the “Test groups” dialog window and select the correct Test Group (<Measure><Test groups>).

   Open the “Measure” menu to reinitiate the start procedure. Confirm Test Group selection by pressing **<Enter>**.

Once the Test Group selection has been confirmed as being correct, the instrument checks for expired reagents. If one or more reagents are beyond the programmed expiration date, the “Expired Reagents” window is displayed.

[Expired Reagents]

```
Reagent  Lot      expired
ALEXIN   45H6214  10/31/95




   Start run ?  NO
```

Any expired reagents are listed. Check actual reagent expiration date.

1. If the reagent is expired and you want to replace it now, answer the “Start run?” question by pressing <Enter>. The start procedure is interrupted. Prepare fresh reagent or start a new unexpired lot number. Update the lot number and expiration date in the appropriate Reagent Definition dialog window. Reagent Definition is discussed in Section 19.4, System, Parameter, Reagent.

19.4.1

ATTENTION!
The reactivity of expired reagents is unreliable. Do not use unreconstituted reagents beyond the listed expiration date. Do not use reconstituted reagents beyond established stability claim limits.

2. If the reagent is not expired or you don't want to replace it now, answer the “Start run?” question by pressing **<y><Enter**.

If **Positive-Id is not active,** a window asking for confirmation of the sample tray that will be processed is opened. The sample tray number being displayed will be the first tray with unprocessed samples on it.

```
Sample tray number   :   #
Confirm   :   NO
```

Three function keys are active with this display and are listed at the top of the screen.
<F1>: Reagent – used to open the reagent overview window
<F2>: Sample – used to check the sample overview window
<F3>: Trays – used to select a tray

If the sample tray number being displayed is correct, confirm with **<Enter>**.

If the tray number is not correct:
1. Type in the correct tray number and confirm with <y><Enter>; or
2. Press **<F3>** to open the “Select tray” window.
   Move the cursor to the desired tray and press **<Enter>**.
   Press **<Esc>** to exit the window and return to the “Sample tray” screen.
   Confirm selection with **<y><Enter>**.

If the tray number that is confirmed is valid and has unprocessed tests loaded on it, the QC evaluation registers are updated and testing is started.

If **"Positive-Id" is active**: after updating the QC evaluation registers, the instrument scans all the sample barcodes until a sample is found that has unprocessed tests. The search always starts from tray position 1. A full tray search may take up to 5 minutes. For a fast start-up, avoid positioning unprocessed samples at the end of the tray.

If **"Positive-Id" is active**: If a new Test Group has been selected or if this is the first processing period for this Test Group, the instrument starts the processing cycle by checking reagent levels. Since the sample requisitioning is done through the LIS, the instrument assumes any test assigned to the Test Group may be requested. All reagents must always be present. If one or more reagents, including cleaner, assigned in the Reagent layout for the Test Group are missing or are below the programmed required minimum volume, processing is interrupted. The alarm will sound, the "Reagent overview" window will be automatically displayed and the reagent status field at the bottom of the Main Menu will be red with the message "Refill reag.".

If "**Position oriented"** is active: If a new Test Group has been selected or if this is the first processing period for this Test Group, the instrument starts the processing cycle by checking reagent levels. If one or more reagents, including cleaner, essential for the currently requested tests are missing or are below the programmed required minimum volume, processing is interrupted. The alarm will sound, the "Reagent overview" window will be automatically displayed and the reagent status field at the bottom of the Main Menu will be red with the message "Refill reag.". If reagent(s) assigned to the Reagent layout are missing but the tests utilizing these reagents are not requested, processing will continue but tests utilizing the missing reagent(s) will no longer be available in this processing period. The tests will not be displayed on the Quick-Start screen and will be displayed in blue in the "Add" screen

Any time reagents that the instrument considers essential are missing or are below the defined minimum volume, the alarm sound, the "Reagent overview" window will be automatically displayed and the reagent status field at the bottom of the Main Menu will be red with the message "Refill reag."

1. Turn the alarm off by pressing **<Alt-F2>**.
2. The "Reagent overview" window will be displayed. Reagents with insufficient volumes will be flashing red. Note that if the cleaner level is below the minimum volume requirement, none of the other reagents will be checked.

ATTENTION!

Continued repeated addition of new reagent to old reagent may lead to changes in the reagent composition that may change its reactivity. It may also lead to microbial contamination that will seriously compromise reagent stability. Reagent containers that are reused should be thoroughly decontaminated with 10% bleach, rinsed in tap water, rinsed in DI water and dried prior to reuse.

3. Replenish reagents and Enzyclean as necessary. Replace cover when finished.

ATTENTION!
Enzyclean is the recommended system cleaner. To avoid compromising precision and accuracy, water or other unrecommended fluids should not be used.

4. Press **<Esc>** to exit from the "Reagent overview" window.
5. Restart processing: **<Measure><Start>**.

   The cover to the reagent/sample tray must be on at the start of processing. Although it may be removed after processing has begun, the cover must be in place before processing will start. To facilitate temperature regulation within the reagent/sample storage area, it is recommended that the cover be on except when actually working in the storage area. The following message will appear at the top of the screen:

```
Warning!          Close lid
```

   Replace the cover. Processing will begin.

15.5 Graphic

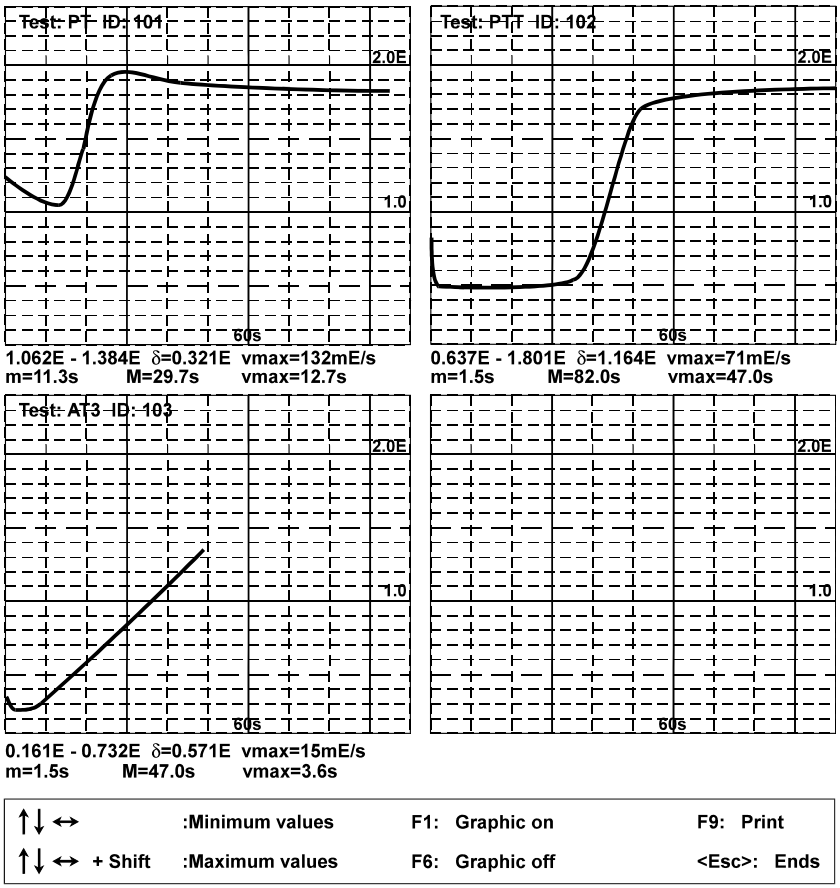
Password security system = unrestricted
PIN security system = unrestricted

The graphics mode allows real-time observation of photo-optical and chromogenic test reactions. The graphic reaction representations are stored in the patient file and may be retrieved and printed out with the patient report.

The graphics mode is useful when developing new tests and may provide useful information when troubleshooting.

The default setting for the graphics mode is OFF. Storage of the graphic representations requires large amounts of disc storage space in the patient files and will limit the number of patient files that may be archived. In addition, when operating in graphics mode each reaction is measured for the entire programmed timeout period. Throughput will be affected. Use of the graphics mode is not recommended as a normal operating procedure. Activation only under special circumstances is recommended.

To enter the graphics mode: With the "Measure" menu open, press **<g>** or move the cursor to **"Graphic"** and press **<Enter>.** The graphic display window opens.



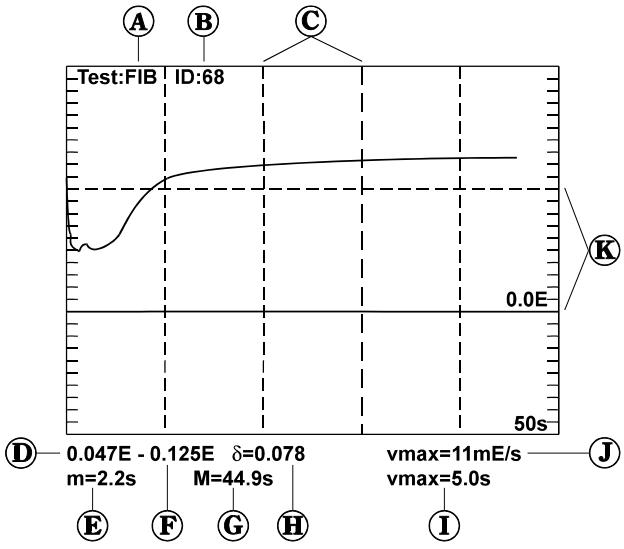
The display area is divided into four areas that represent each of the four optical measuring wells. The graph on the upper left is Optical Measuring Well # 4 (well closest to the front of the instrument). The graph on the lower right is Optical Measuring Well # 1 (well farthest from the front, closest to the incubation rail). The

instrument always preferentially uses Optical Well #4 if it is empty. When the window is first opened and graphics have not been activated, the graphs will be empty. If graphics are active and optical measuring is taking place, the ongoing reaction will be depicted. If graphics are active but no optical measuring is taking place, the last measured reactions will be depicted.

Instructions for use of the window are displayed at the bottom of the window.

Graphics Mode Commands	
<Arrow keys>	Used to set the minimum values of the graphic representation (time and absorbance)
<Shift> + <Arrow keys>	Used to set the maximum values of the graphic representation (time and absorbance)
<F1> Graphic on	Activates the graphics mode. All subsequent optical tests will be followed graphically and the graphic information will be stored in the respective patient files. The graphics mode remains active until it is either deactivated or the instrument is powered down
<F6> Graphic off	Deactivates the graphics mode
<F9> Print	Used to print a hard copy of the graphics. The <Print Scrn> key is not active in this window
<Esc> Ends	Closes the graphics display window. Does not deactivate graphics mode

The graphic depiction not only shows the reaction but also indicates information about the characteristics of the reaction.



Graphics Interpretation	
Code	**Description**
A	Test that is being measured
B	Sample ID
C	x-axis division. 1 unit = 10 seconds
D	Minimum absorbance (mE)
E	Minimum absorbance time (seconds)
F	Maximum absorbance (mE)
G	Maximum absorbance time (seconds)
H	Maximum delta absorbance (mE)
I	Maximum slope time (seconds)
J	Maximum slope (mE/second)
K	y-axis division. 1 unit = 100 mE

The graphic display and associated reaction information are very useful when developing and optimizing test parameters. It may also be of assistance when troubleshooting unexpected results on particular patient samples. The display depicts exactly what the photometer sees. The instrument uses the reaction characteristics in conjunction with programmed test parameters to determine the final result.

15.6 Pause, Stop and Abort

Password security system = unrestricted
PIN security system = unrestricted

Processing may be interrupted or terminated at any time.

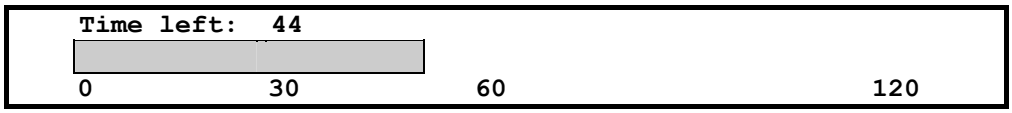
Processing may be discontinued in three ways that differ in what happens when processing stops:

1. **Pause:** Interruption of processing for a brief period of time. Processing is resumed on command at anytime within the allotted time interval.
2. **Stop:** Sampling is processing stopped but tests currently in progress are completed.
3. **Abort:** All is terminated immediately. Tests currently in preparation or incubation are not completed. Tests in the measuring wells are completed.

15.6.1 Pause

The "Pause" procedure temporarily interrupts processing. Pausing allows the addition of samples or reagent without having to dodge the robot or keep up with the moving trays. "Pause" is a limited time procedure.

With the "Measure" menu open, press **<p>** or move the cursor to **"Pause"** and press **<Enter>**. The "AMAX200-Pause" window (countdown screen) is displayed.

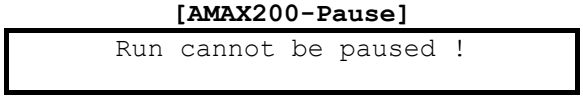


A time bar shows the time in seconds that is available to do tasks. The time shown is dependent on the remaining incubation time for the next test currently in process. At the end of the indicated time, the instrument is scheduled to either add reagent or move the next test to a measuring well.

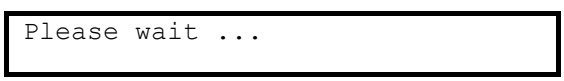
The robot moves to the far right to its park position just to the right of the last measuring well. This allows unobstructed access to the reagent/storage area. The sample and reagent trays move to the home position.

Perform sample and/or reagent addition. When finished, press **<any key>** to continue processing.

There will be occasions when the time before the next scheduled instrument task is too short for the operator to do anything. The following message will be displayed:



After a short time, this screen will be replaced by the "Please wait" screen.



When there is time for you to do something, the countdown screen will be displayed showing how much time you have to accomplish your work.

15.6.2 Stop

The “Stop” procedure stops sampling. No new tests will be started. Tests currently in process are completed which ends the processing period.

With the “Measure” menu open, press **<o>** or move the cursor to **“Stop”** and press **<Enter>**.

15.6.3 Abort

The “Abort” procedure stops all processing. No new tests will be started. Tests currently in the preparation or incubation phases are terminated. Tests in the measuring wells are completed.

There is an immediate audible alarm. Turn the sound off by pressing **<Alt-F2>**. The “Abort confirmation” screen will be displayed.

```
Confirm:   NO
```

If you do want to stop all processing, press **<y><Enter>**. If you do not want to lose all tests currently in process, press **<Enter>**.

If the run is aborted, a warning message appears at the top of the screen:

```
ABORT          Run aborted

                                      Press any key
```

Press **<any key>** to clear the message.

Cuvettes positioned in the incubation rail containing tests in process are transported to the last optical measuring well (well # 4 – closest to front of instrument) and discarded.

16 STAT MENU 16-1
16.1 QUICK-START 16-1
16.2 STAT POSITION 1 - 8 16-1
16.2.1 Stat Requisitioning 16-2
16.3 MONITORING AND PRINTING STAT RESULTS 16-4
16.4 EMPTYING STAT POSITIONS AND TRANSFERRING DATA TO ARCHIVE 16-4
16.5 END 16-5

The “Stat” menu is used to by-pass the “normal” operating sequence. Virtually all laboratories have incoming samples that must be processed quickly. Many laboratories have continuously arriving samples. Another characteristic of many laboratories is a staff with differing levels of training. The “Stat” menu has been designed to facilitate all these circumstances.

16.1 Quick-Start

Password security system = unrestricted
PIN security system = unrestricted

“Quick-Start” is an alternative operation mode designed to minimize operator interaction with multiple screens. Since it is so easy to use, Quick-Start may be utilized very effectively by minimally trained or transient operators. It is also very useful in laboratories with continuous sample arrival.

The number of commands needed to operate the AMAX 200 has been reduced to an absolute minimum. Because a single dialog window is used, some features are not available in the Quick-Start operation mode. Operation in the Quick-Start mode is discussed extensively in Section 9.

9

16.2 Stat Position 1 - 8

When using the normal operating mode, Stat samples are requisitioned using the “Stat” menu. Up to 8 Stat samples may be run at one time. Barcodes are not used. Stat samples may only have tests ordered that are in the currently active Test Group. Stat ID and result information is stored in temporary Stat files. All information is transferred to the patient archive files when the position is cleared.

19.1

Stats are sampled from the Reagent Tray, not the Sample Tray. The number of Stat positions (1 to 8) is defined in the Reagent Layout. If no Stat positions are assigned to the Reagent Layout assigned to the currently active Test Group, there will be no Stat positions listed as options when the “Stat” menu is opened. When Stat positions are assigned to the layout, the number of positions assigned is reflected as options when the “Stat” menu is opened.

19.3.1.C

[No Assigned Stat Positions]

```
Quick-Start
```

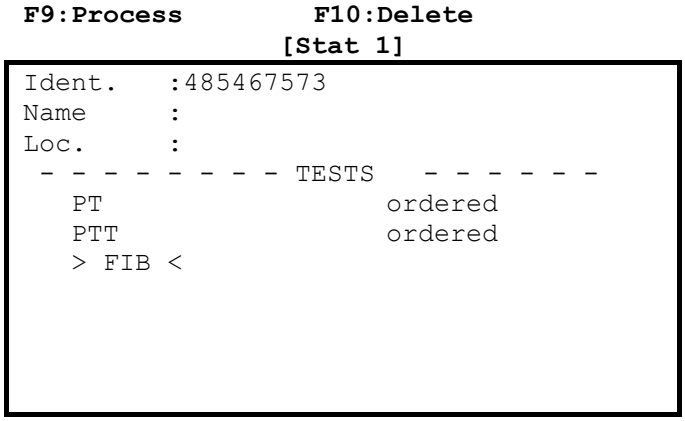
[Assigned Stat Positions]

```
Quick-Start
1. Position
2. Position
3. Position
4. Position
```

Note that the numbers displayed do not necessarily indicate the actual tray position. The numbers only indicate that there are four Stat positions, not where they are located. For example: In the above display there are four stat positions available. These four positions may or may not be tray positions 1, 2, 3 and 4. The location is determined in the reagent layout definition and may be viewed from the Overview, Reagent screen.

16.2.1 Stat Requisitioning

A. With the “Stat” window open, move the cursor to “1. Position” and press **<Enter>**. The dialog window “Stat 1” is displayed.



B. Entry of a sample identification is mandatory. Entry of the name and location is optional. Type in **<Sample ID>** followed by **<Enter>**. Name and location may either be entered in the same manner or by-passed by pressing **<Enter>**. To bring up a location listing, type **< . ><Enter>**. Move the cursor to the appropriate location and press **<Enter>**.

C. Using the **< ↓ >** key, move the cursor into the “TESTS” section. The only tests that will appear in the display are those assigned to the currently active Test Group. Move the cursor to the appropriate test(s) using the < ↓ > and < ↑ > keys. Press **<Enter>** to confirm selection. The message displayed opposite the selected test is determined by the definition of Error Code 0 (refer to Section 18.8.2). Pressing **<Enter>** with the cursor over a test that has been ordered will deselect the test.

D. Press **<F9>** to begin processing.

What happens next depends on whether or not the instrument is processing; and, if processing, whether it is at a time when processing may be paused.

If the instrument is not currently processing:

```
          [Start-Test group]
Name     :ROUTINE
Group    :4
Reagent  :PT/PTT
          Tests -- Replicate
   1: PT-0         Single
   2: PTT-0        Single
   3: FIB          Duplicate
   4:
   5:
   6:
   7:
   8:
   9:
  10:
  11:
  12:
  Confirm :   YES
```

If for any reason you are not ready to start processing, press **<n><Enter>**.

If you are ready to start processing, press **<Enter>**.

If the instrument is processing, the message that appears is dependent on how much time the instrument has before it is scheduled to do its next task.

If the time for an upcoming scheduled task is close and there isn't time for the instrument to interrupt the processing and still do the task:

```
      Run cannot be paused !
```

After a short time delay, the “Please wait . . .” screen is displayed.

```
        Please wait  . . .
```

As soon as it finishes whatever it was doing and processing may be paused, a time bar screen is displayed. “Pause” is a limited time procedure. The time you have to complete the Stat sample addition is indicated on the screen.

Make a mental note of the time remaining and press **<any key>** to clear the screen.

```
    New samples added  ?   YES
```

The robot moves to the far right. Position Stat sample into the programmed position in the outside ring of the Reagent Tray.

If for any reason you are not ready to start processing, press **<n><Enter>**.

If you are ready to start processing, press **<Enter>**.

A. A request for confirmation of the sample tray is displayed.

```
Sample tray ID  :   1
Stat (Flashing)
Confirm
```

Press **<Esc>** to confirm. Processing resumes. The stat sample will be the next sample processed.

16.3 Monitoring and Printing Stat Results

1. To monitor the test results for a Stat sample:

   Open the "Stat" menu and select the position of the Stat results you want to monitor.

```
Ident. :485467573      locked !
Name   :
Loc.   :
   - - - - - - - - TESTS - - - - - - - -
PT                 14.9
PTT                88.3
FIB                Not processed
```

2. To print the results, press **<Print Scrn>**. A sample cannot be printed using the "Result list" or "Report" options until the sample has been deleted from the Stat files and transferred to the archive files.

16.4 Emptying Stat Positions and Transferring Data to Archive

Once a Stat position has been used, it is locked and cannot be re-used until the data is transferred out of the Stat files and into the patient archive files.

A Stat cannot be deleted (transferred to the archive) while it is processing. Once processing on the Stat is completed, it may be deleted (transferred) to open the position to accommodate additional Stat samples. Deleting the sample from a Stat position does not delete ID and result information. All information is transferred to the patient archive.

Press **<F10>** to delete the Stat sample from the Stat file. Confirm **"Delete stat sample? NO"** with **<y><Enter>**.

All ID and result information is automatically transferred to the patient archive files.

Once the information has been transferred to the archive files, the sample may be recalled and printed using the "Result list" or "Report" options.

17.8
17.10

16.5 End

When testing is completed, the instrument may either be left on to be available for additional testing; or, may be powered down using the End procedure.

If there are Stats programmed when the instrument is asked to exit the AMAX operating program, you are asked to remove any Stat samples.

```
Remove stat samples
```

Press **<any key>** to exit the operating program. The DOS prompt will appear. From the DOS prompt, the instrument may either powered down; or, the operating program may be re-entered by typing **<a><Enter>**.

21

17 PATIENTS MENU.....17-1
17.1 NEW 17-1
17.2 EDIT 17-5
17.3 ADD 17-7
17.4 REPEAT 17-10
17.5 IMPORT 17-12
17.6 EXPORT 17-12
17.7 PATIENT LIST 17-13
17.8 RESULT LIST 17-13
17.9 RESULTS LIST ON-LINE 17-15
17.10 REPORT 17-15

Patients Menu

All options in the “Patient” menu are used to associate specific sample information with processing. The options are used to enter demographic information about samples; to instruct the instrument on what to do to each sample; to associate multiple individual results to each sample; and to provide a collated report of the results. Transfer of this information may either be direct using the keyboard or barcodes; or, indirect through a LIS interface.

To open the “Patients” menu, either press **<p>** or move the cursor to **“Patients”** and press **<Enter>**.

[Patients]

```
New
Edit
Add
Repeat
Import
Export
Patient list
Result list
(Result list on-line)
Report
```

Section 17.1: New
Section 17.2: Edit
Section 17.3: Add
Section 17.4: Repeat
Section 17.5: Import
Section 17.6: Export
Section 17.7: Patient list
Section 17.8: Result list
Section 17.9: (Result list on-line)
Section 17.10: Report

17.1 New

Password security system = unrestricted
PIN security system = unrestricted

1. The “New” option is used to identify new samples and to register the associated test requests.

   Open the “New” dialog window: Press **<n>** or move the cursor to **“New”** and press **<Enter>**.

[Enter new samples]

```
Seq. number   :6
Tray/Posit.   :3/4
Ident.  :485467573
Name    :
Loc.    :
Note    :
 - - - - - - - - TESTS - - - - - - - -
PT      PTT   FIB   AT
```

Key	Description
Seq. number	Position in patient archive file. Instrument assigned.
Tray/Posit.	Sample tray that will be used and position in that tray. Selectable entry. Only appears when "position oriented" identification is selected.
Ident.	Unique sample identification (20 alphanumeric character limit). Mandatory entry.
Name	Additional identification information. Optional entry.
Loc.	Location of patient. Optional entry.
Note	Comments about sample or patient. Optional entry.
Test area	Test(s) requested. Selectable entry.

2. When "Positive Id" is on: No tray number or position number is assigned. Barcoded samples may be placed anywhere in a sample tray.

   When "Positive Id" is not on (position oriented identification): A tray and position number are assigned to each sample, which correlates to its position in a specific tray. The Tray/Position number that is assigned when the dialog window opens is the first tray that has free positions available. This may or may not be the tray that you want to use.

   To change the tray:

   A. Using the <↑> or <←>, move the cursor to the "Tray/Posit." field. The "Select tray" dialog window appears.

[Select tray]

No	No samp.	first ID	last ID	Status
1	60	101	160	finished
2	60	201	260	finished
3	5	301	306	not compl.
4	25	401	425	ready
5	5	304	504	ready
.				free
.				free
17				free

   B. Use the <↓> or <←>, move keys to move to the tray you want to use and press **<Enter>**. Move the cursor to an empty position if you want to start a new tray.

   The display returns to the "Enter new samples" dialog window and the selected tray number will be in the Tray field. The position assigned will be the first open position on that tray. The position may be changed using the "Tray, Load" procedures.

15.2.3

3. How the entry of sample identification, other identifying information and test requests is handled depends on how the system options are set-up. Barcodes supply the sample identification when "Positive Id" is on. Samples are identified through keyboard entry when "position oriented" Id is on. When both "Positive Id" and "Automatic Profile" are on, all tests comprising the selected Test Group will be automatically requested.

18.4

When "Requests only" is active, tests are requested through the keyboard or downloaded from a host computer.

A. If both "Positive Id" and "Automatic Profile" are on: No entries are required. All tests comprising the Test Group will be ordered. This option may be used either alone or in conjunction with a host computer. When not interfaced, entry of additional demographic information is optional and is done using the "Edit" option.

B. If "Positive Id" is on and "Automatic Profile" is off ("Requests only" is on): This option is only effective if interfaced to a host computer. If not interfaced, all "request only" entries are through the keyboard and are, in fact, "position oriented". Manually enter the barcode number in the "Ident." field. Entry of additional demographic information is optional. Test(s) are requested through the keyboard. An off-line barcode scanner may be used to enter the ID.

C. If "Positive Id" is not on: Enter a unique identification number or name. Any alphanumeric combination of up to 20 characters may be used. The designation must be unique. If the ID code is not unique, an audible alert sounds and the message "multiple!!!" appears in the Ident. field.

4. Entry into the "name" (40 character limit), "Loc." (20 character limit) and "Note" (40 character limit) fields is optional. This information may be entered now, never or may be done at your convenience using the patient "Edit" option.

   Press **<Enter>** to by-pass any of these fields.

   "Loc." refers the location of the patient. The location codes may be used to sort patient results. Location codes are defined in Section 18.6, System, Location codes.

18.6

   There are three ways to make entries into the Loc. field:

   A. Type in the full name of the location (20 character limit);

   B. **< . >** (period) or **< , >** (comma) **<defined location code><Enter>**.

   C. **< . >** (period) or **< , >** (comma) **<Enter>** opens the "Location codes" dialog window.

[Location codes]

ER	:	Emergency Room	:
ICU	:	Intensive Care Unit	:
MH	:	Mercy Hospital	:
OP	:	Outpatient	:
PED	:	Pediatrics	:

   Move the cursor to the **<desired location>** and press **<Enter>**. The selected location will be in the "Loc." field.

   Any typed remark (40 character limit) may be entered into the "Note" field.

5. When the test requisition option is set to "Requests only", tests are requested through the keyboard. When "Positive Id" and "Automatic Profile" are both on, all tests comprising the Test Group are automatically requested.

Access the “TESTS” area by pressing **<F3>** or by moving the cursor down into the area below “TESTS”. <F3> may be pressed from any of the fields below “Ident.” to by-pass further information entry and go directly into the test requisition area.

There are several options for how to requisition tests:

A. Enter the test-code or the corresponding test sequence number. It is helpful to have a numbered test list posted close to the instrument.

   Press **<F2>** to advance to the next sample position and to store the information in the archive.

B. Using the numeric keyboard, pressing **<+><Enter>** opens the “Test list” dialog window. All of the available tests are listed.

   Move the cursor to the first test to be requested and press **<Enter>**. The test-code of the selected test will appear in the “TESTS” area.

   Continue with **<+><Enter><desired test><Enter>** until all desired tests have been selected.

   To deselect an ordered test, with the cursor in the “TESTS” area, move the cursor to the selected test and press **<Space><Enter>**. The test will be deselected and no longer appear in the “TESTS” area.

   Press **<F2>** to advance to the next entry position.

C. Recall a listing of pre-defined test panels by pressing **<F8>**. Panels are discussed in Section 18.7, System, Panels. The Panels window will open.

18.7

   Select a panel by typing in **<panel number>**.

   Press **<F2>** to advance to the next entry position.

D. Once tests have been requested on a sample, that particular combination of tests (impromptu panel) may be stored and transferred to subsequent samples.

   Press **<F4>** to store the test combination. This test combination will be automatically requested on every subsequent sample until that combination is modified by either adding or subtracting tests.

   Press **<F2>** to advance to the next entry position.

E. If a particular combination of tests is to be ordered on a **consecutively numbered series** of samples, all tests on a defined number of samples may be entered simultaneously. Type in the ID and request tests on the first sample in the series. As soon as all tests have been requested, press **<F5>** to open the “Multiple samples” dialog window.

```
Total number of samples: _ _
```

   Enter the total number of samples (inclusive of the one already entered) to be numbered consecutively and have the same tests ordered. Complete the request with **<Enter>**. All of the samples will have a sample ID incremented by 1 (if the last character in the first sample ID is a letter, a numerical increment will be added). If you change your mind, press **<Esc>** to exit the screen.

   The next available empty position will be displayed.

F. Continue as above until all samples have been entered.

Patient, New: Function Key Summary	
Function Key	**Description**
<F2>: Advance	Completes and stores the entries of the current sample and advances to the next sample position.
<F3>: Tests	Moves cursor into the "TESTS" field.
<F4>: Store panel	Stores an impromptu or pre-defined panel containing the combination of tests ordered on a sample. When <F2> is pressed, the stored panel is automatically requested on the next sample.
<F5>: Multiple samples	Stores an impromptu or defined panel and replicates the panel for a specified number of samples. The ID increments by 1 for every sample in the series.
<F8>: Panel	Opens the "Panel" dialog window used to select a pre-defined panel of tests.

17.2 Edit

Password security system = unrestricted
PIN security system = unrestricted

The "Edit" option is used either to change or to add information. The most common uses are to add demographic information after processing has already begun and to order additional tests.

1. To open the "Edit" dialog window: Press **<e>** or move the cursor to **"Edit"** and press **<Enter>**.

[Modify samples]

```
Modify sample-ID code  :  (ID Code)
```

Enter the ID code of the first sample to be modified. Press **<Esc>** to complete. The "Modify samples" dialog window is displayed. This window is identical to that used for entry using the "New" option. It will contain whatever information has already been entered about the requested sample. Use of **<F1:Back>** and **<F2:Advance>** allows movement forwards and backwards through the files.

2. Move through the window making entries in the same manner as described for "New". All previously entered information may be altered.

   If the sample ID code or the name is changed, a warning is displayed asking for confirmation of the change:

[Caution]

```
Change ID code?    NO
```

[Caution]

```
Change the name?    NO
```

Confirm with **<y>**<Enter>. Deny with **<Enter>**.

ATTENTION!
All printouts on altered ID codes or names will be marked with an *****.

3. **Edit Results**. Once tests have been processed, when the cursor is in the "TESTS" area and positioned over a test, the results of that test are displayed at the bottom of the "Modify samples" dialog window.

```
 F1: Back      F2:Advance    F3:Tests      F9:Edit Result
                             [Modify samples]
Seq. number   :6
Tray/Posit.   :3/4
Ident.  :485467572
Name    :
Loc.    :
Note    :
     - - - - - - - - TESTS - - - - - - - -
PT      PTT   FIB      AT



-------------------------------------------------------------------
Value   :680.8          %:  32        mE:680.8
Dil.    :40
```

The processed results of any test may be irreversibly replaced with a pre-defined error code. The result cannot be altered to another number. It may only be replaced with an error code. The original result cannot be re-entered.

18.8.2

With the cursor over the test you want to flag with the error code, press **<F9>**. The cursor will move to the "Value" area. **< - ><Error code #>**. The value results are replaced by the error code number and the associated message.

```
 F1: Back      F2:Advance    F3:Tests      F9:Edit Result
                             [Modify samples]
Seq. number   :6
Tray/Posit.   :3/4
Ident.:485467572
Name  :
Loc.  :
Note  :
     - - - - - - - - TESTS - - - - - - - -
PT    PTT     FIB      AT



-------------------------------------------------------------------
Value : -8              Transport delay
```

17.3 Add

Password security system = unrestricted
PIN security system = unrestricted

The “Add” option is used to add samples to a worklist. Samples may be added to a worklist before or after processing has started. This is a very quick way to add samples and get them into the current processing period. No demographic information other than sample-ID may be entered. Such information may be entered using the “Edit” option after incorporating the new samples into the processing period.

1. To open the “Add” dialog window: Press **<a>** or move the cursor to **“Add”** and press **<Enter>**.

F1:Tray F2:Auto Inc. F9:Process F10:Undo

√ Auto Inc.	Pos	R #	PTO	PTTM	FIB	AT	F8	F9	HEP	PTM	TT			
286_____	1	2	*	*										
287_____	2	2	*	*	*									
289_____	3	2			*						*			
290_____	4	2	*											
123_____	5	2		*		*			*					
124_____	6	2	*							*				
125_____	7	2					*	*						
_____	8	2					*	*						
_____														

   If the instrument is currently processing, it assumes that you want to add samples to the tray currently in use. A different sample tray may be selected (but not processed in the current processing period) by pressing **<F1>**. The “Select tray” dialog window will appear. Move the cursor to the tray you want to add samples to and press **<Enter>**.

   To have the sample IDs automatically increment by 1 number, press **<F2>**.
   A √ -mark appears in front of “Auto Inc.”. If you don't want the ID to automatically increment, press **<F2>** to remove the √ mark.

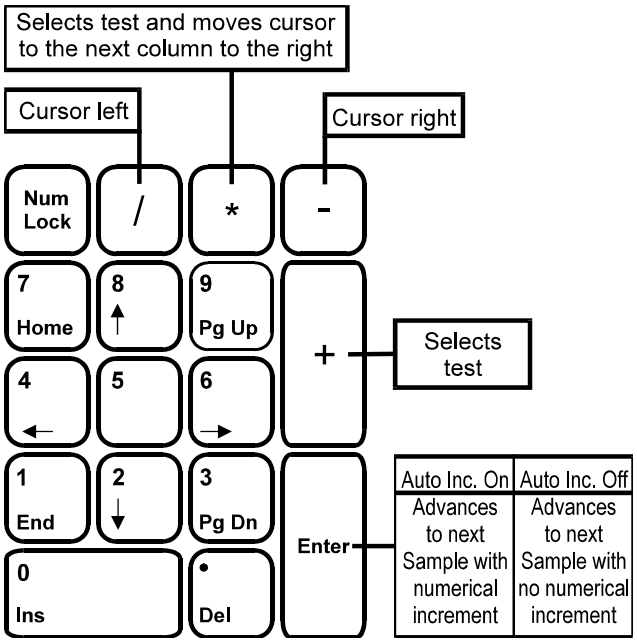
2. To add samples:

   A. Type in the **<sample ID code>**. Complete with **<Enter>**. The cursor will move into the test selection columns.

   B. A column is reserved for each defined test. Tests that are in the current Test Group and may be processed during the current processing period are highlighted red. Other tests (displayed in blue) may be requested but will not be processed in the current processing period.

      The <arrow> keys are one way to move about in the test requisition area. Another, and usually more efficient way, is to use the numerical keypad. The numerical keypad is used to facilitate rapid test selection and movement through the dialog window. The set-up is the same as that used in Quick Start.

      Order tests as described below.



The <Num Lock> indicator light must be illuminated.

< / > moves the cursor one column to the left

< - > moves the cursor one column to the right

< * > orders the test assigned to that column and advances the cursor one column to the right

< + > orders test assigned to column

<F8> brings up a listing of defined panels. Type in the **<Panel #><Enter>**.

C. When a test is ordered, an " * " is inserted into the test column for that sample. The " * " will be red if the test is in the currently selected Test Group and may be processed during the current processing period. The " * " will be yellow if the test is not part of the currently selected Test Group. The test may be ordered but it will not be processed until a Test Group containing that test is selected.

D. If a test is ordered accidentally or if you change your mind, pressing the **<Spacebar>** deletes an ordered test.

E. Once tests have been ordered on a sample, there are several options for proceeding. Which option to use is dependent on the next sample.

<Enter> or < ↓ >: If Auto Inc. is checked, advances the cursor to the next sample identification position with numeric increment. If Auto Inc, is not checked, advances to the next sample identification position ready for entry of the next sample ID.

<Shift>+<Enter>: or **<Shift>+< ↓ >**: If "Auto Inc." is off and the next sample has been identified, copies the tests ordered on the current sample to the next sample. If "Auto Inc" is on and the sample has not been identified copies the tests and the next consecutive number will be automatically assigned as the ID-code.

F. Continue as above until the appropriate identification and tests have been completed.

3. After all new samples have been added, there are three options to choose from that determine what happens next.

A. Exit window without starting processing: Press **<Esc>** to confirm and store in patient archive file. The new samples may be processed in a later processing period.

B. To incorporate the newly added samples into the current processing period or to start a new processing period, press **<F9>**. Whether or not the samples will be included in the current processing period depends on the stage of current processing. Samples are processed in small batches determined by the group size defined for the Test Group.

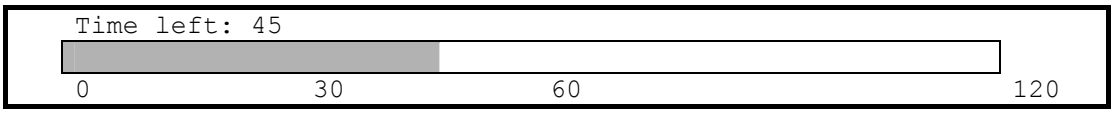
If the last batch is already in process, the new samples will not be incorporated into the current processing period. Restart at the conclusion of the processing period.

When **<F9>** is pressed, the instrument automatically goes into "Pause" mode. The robot moves to the far right to allow easy access to the reagent/sample tray storage area. One of the "AMAX200 – Pause" windows will be displayed. Which one is displayed first depends on just when the instrument is scheduled to do upcoming tasks.

```
Run cannot be paused !
```

The instrument doesn't think there is time for you to do anything. After a short time delay, a screen is displayed asking you to wait and then shows how much time you have to add samples.

```
Please wait . . .
```



Press **<any key>** to clear the screen. An alarm will sound if the time gets down to 10 seconds.

```
New samples added  ?   YES
```

Press **<any key>** to clear the screen.

The tray load map is displayed with the new samples to be added highlighted in a red field. Place samples in designated positions.

[Position New Samples]

1	223	21	41
2	224	22	42
3	225	23	43
4	226	24	44
5	418	25	45
6	419	26	46
7		27	47
8		28	48
9		29	49
10		30	50
11		31	51
12		32	52
13		33	53
14		34	54
15		35	55
16		36	56
17		37	57
18		38	58
19		39	59
20		40	60

Press **<Enter>** to begin processing. Press **<Esc>** to cancel. Processing will resume with incorporation of the new samples into the current processing period if processing has not already started on the sample batch of which they are a member.

C. If you decide you really don't want to add these samples at this time, press **<F10>**. The entire addition worklist will be deleted.

17.4 Repeat

Password security system = unrestricted
PIN security system = unrestricted

The "Repeat" option is used to request repeat testing on already processed samples. It may also be used to request new tests on already registered samples and to add new samples.

When a test is repeated, the new result replaces the previous result in the patient archive file. The old result will no longer be retrievable.

1. To open the "Repeat test" window, press **<p>** or move the cursor to **"Repeat"** and press **<Enter>**.

```
Test: = = = = =
```

2. To select test to be repeated, type in:
   A. <Test code> or <test number> followed by <Enter>; or,
   B. Press <+><Enter> to bring up the "Test list" window.

[Test list]

```
PT    Prothrombin Time
PTT   aPTT
FIB   Fibrinogen
TT    Thrombin Time
ATX   Atroxin
AT    Antithrombin
F8    Factor VIII
F9    Factor IX
HEP   Heparin
```

   Move cursor to desired test and press **<Enter>**.

3. The "Repeat test" dialog window for the selected test opens.

[Repeat test]

```
Test: PT
1: 223            16:
2: 224            17:
3: 419            18:
4: *595           19:
5:                20:
.                 .
.                 .
15:               30:
```

Type in the ID codes of the samples:

A. Previously processed tests may be repeated.

B. Additional tests on old samples may be requested.

C. New samples may be added. New samples will be marked with an *. New samples will be marked on the repeat listing with an " * ". New samples must be assigned a tray position (<Patient><Edit> or <Tray><Load>) prior to starting processing.

Note that the number opposite the ID-code is **not** the sample tray position. The number signifies how many repeats or other additional testing is to be done. Samples processed previously that already have an assigned position in the sample tray remain in that position.

4. Press **<Esc>** to confirm the repeat request and to store the requests in the patient archive file. If, for any reason, you decide not to go ahead with the repeat requests, press **<F9>** to delete the repeat worklist. The entire worklist will be deleted.

5. Processing on the repeat worklist is done in the usual manner. Select an appropriate Test Group. Start processing with **<Measure><Start>**. Select the tray containing the repeats.

If **"Positive Id" is off**, a load map showing the positions of the repeat worklist samples is displayed. The unprocessed samples are highlighted in red.

1:	223	21:	41:
2:	224	22:	42:
3:	225	23:	43:
4:	226	24:	44:
5:	419	25:	45:
6:	420	26:	46:
7:	595	27:	47:
8:		28:	48:
9:		29:	49:
10:		30:	50:
.		.	.
.		.	.
20:		40:	60:

Assure that the appropriate samples are in the highlighted positions. Press **<Enter>** to begin processing. Press **<Esc>** to abort processing.

ATTENTION!
When "Positive Id" is not on, always check the physical position of each sample to assure correct positioning.

If "Positive Id" is active, the instrument scans all sample barcodes until a sample is found that has unprocessed tests (once scheduled for repeat testing, the tests to be repeated are considered by the instrument as "unprocessed"). The search always starts from tray position 1. A full tray search may take up to 5 minutes. For a fast start-up, avoid positioning unprocessed samples at the end of the tray.

17.5 Import

Password security system = unrestricted
PIN security system = unrestricted

The “Import” option is used to transfer data from a LIS to the AMAX 200. Data is transferred according to the bidirectional protocol.

When the “Import” option is accessed by pressing **<i>** or by moving the cursor to **“Import”** and pressing **<Enter>**, a window opens that displays the status of the communication interface.

```
                    [Host - Status]
Import   :active                  Samples: 0
                                  Tests:   0
Export   :- - - -                 Data :


Communication  :waiting
Host buffer    :0
```

Press **<any key>** to close the window. The “Host status” window may also be recalled at any time using **<Alt-F3>**.

With software versions 3.1.13 and above, Lis status is always indicated in the right corner of the status bar. When data is being received, “Imp” (blinking yellow on white background) is displayed. If “Imp” is displayed blinking yellow on a red background, data is being imported after a failed attempt.

17.6 Export

Password security system = unrestricted
PIN security system = unrestricted

The “Export” option is used in conjunction with a bidirectional interface to transfer data from the AMAX 200 to a LIS system. The “Host status” window may be recalled at any time using **<Alt-F3>**.

When the “Export” option is accessed by pressing **<x>** or by moving the cursor to **“Export”** and pressing **<Enter>**, the “Export” window is displayed.

```
Export patient file
               Confirm:NO
```

With a bidirectional interface, results are transferred to the LIS according to the bidirectional protocol. Confirm data transfer with **<y><Enter>**.

With software versions 3.1.13 and above, Lis status is always indicated in the right corner of the status bar. When data is being transmitted, “Exp” (blinking yellow on white background) is displayed. If “Exp” is displayed blinking yellow on a red background, data is being transmitted after a failed attempt.

With a monodirectional system, the “Export” option is not used to transfer results. The result list is transferred using the “Result list on-line” option in the “Patients” menu. The “Result list on-line” option is only available if the system has been installed monodirectionally.

17.7 Patient List

Password security system = unrestricted
PIN security system = unrestricted

"Patient list" is used to printout demographic and requisition information on all samples in the patient archive.

To print the complete patient file: Press **<l>** or move the cursor to **"Patient list"** and press **<Enter>**. Since the entire file is printed, this may be a lengthy process and confirmation of the request is required. A window requesting confirmation is displayed when "Patient list" is accessed.

```
Print patient list ? NO
```

To print the patient list, confirm with **<y><Enter>**. To deny the print request, press **<Enter>**.

The printout will contain the following information:

- Instrument processing sequence number
- Sample ID code
- Sample name (if entered)
- Location (if entered)
- Test(s) requested

17.8 Result List

Password security system = unrestricted
PIN security system = unrestricted

The "Result list" option prints out a collated listing of the results on selected samples. When results are printed out in real-time during processing, the results for each sample are printed as soon as all the tests currently being processed on that sample are completed. Real-time results are not printed according to ID number or tray position. Completion of all tests currently being processed on a sample determines the real-time print order. The "Result list" option provides a means of getting all the test results on each sample together in one listing as well as in archive sequence order. This is very helpful when reviewing results prior to final reporting and may also be used for hard-copy record keeping. Only the final result(s) as specified in Test Parameters/Data Reduction (refer to Section 19.2.4) is printed. Individual results (e.g., duplicate times or mEs) are only printed real-time.

To open the "Result list" dialog window: Press **<r>** or move the cursor to **"Result list"** and press **<Enter>**.

[Result list]

```
Loc.  :
from  :
to    :
Confirm :   NO
```

Loc.:	location of patient
from:	first sample ID to be printed
to:	last sample ID to be printed
	Confirmation request

1. Entry into the "Loc." field is optional. "Loc." refers to the location of the patient. When location information is entered, only samples with the specified location will be printed. When location information is not entered, all-inclusive samples within

the specified range will be printed. The entry procedure is the same as that used for entry of patient demographic information.

If printing by location is not desired, press **<Enter>** to by-pass.

Location codes are defined in Section 18.6, System, Locations.

18.6

There are three ways to make entries into the location field:

A. Type in the full name of the location exactly as entered in the new patient location field.

B. **< . >** (period) or **< , >** (comma) **<defined location code><Enter>**.

C. **< . >** (period) or **< , >** (comma) **<Enter>** opens the "Location codes" dialog window.

[Location codes]

ER	:Emergency Room	:
ICU	:Intensive Care Unit	:
MH	:Mercy Hospital	:
OP	:Outpatient	:
PED	:Pediatrics	:

Move the cursor to the **<desired location>** and press **<Enter>**. The selected location will be in the "Loc." field.

2. Move the cursor to "from:". Type the sample ID for the first sample to be included in the printout. Complete with **<Enter>**.

ATTENTION!
If an invalid entry or no entry is made in this field, all results from the beginning of the patient archive up to the specified "to" ID will be printed.

3. The cursor advances to "to:". Type the sample ID for the last patient to be included in the printout. Complete with **<Enter>**.

ATTENTION!
If an invalid entry or no entry is made in this field, all results starting from the specified "from" ID to the end of the patient archive will be printed.

4. The cursor advances to "Confirm: NO". If everything is acceptable (pay particular attention to the entries for "from:" and "to:"), confirm by pressing **<y><Enter>**.

Printout of the collated results on the inclusive sample ID's commences.

17.9 Results List On-Line

Password security system = unrestricted
PIN security system = unrestricted

The “Results list on-line” option is only available if the instrument has been installed in monodirectional interface mode.

Use according to the monodirectional protocol.

17.10 Report

Password security system = unrestricted
PIN security system = unrestricted

The “Report” option is used to print a formal report. The format of the report is defined in Section 18.8, System, Report format.

18.8

1. To open the “Report” dialog window: Press **<t>** or move the cursor to “Report” and press **<Enter>**.

[Report]

Loc. :	
from :	
to :	
all ?	NO
Graphic ?	NO
Confirm :	NO

Loc.:	location of patient
from:	first sample ID to be printed
to:	last sample ID to be printed
all?	unprinted and previously printed?
Graphic?	include reaction graphic?
	final confirmation request

2. The procedure for making entries into the “Loc.”, “from” and “to” fields is the same as that outlined above in “Result list”, Section 17.8. The same cautions for invalid or no entry into the “from” and “to” fields apply.
3. The “all” option is used to differentiate between previously printed reports and unprinted reports.

   The confirmation choices are:

   A. To print out all inclusive ID reports regardless of whether or not a previous report has been printed, press **<y><Enter>**.

   B. To print out only the inclusive ID reports that have not been previously printed, press **<Enter>**.
4. The “Graphic” option is used to print out the reaction graphic along with the formal report. In order for graphics to be printed, the graphic mode must have been activated prior to test measurement.

15.5

ATTENTION!
Because throughput is decreased and because of the large amounts of disc space required to store graphic reaction representations, routine operation with the Graphic mode active is not recommended.

The graphic printout confirmation choices are:

A. To print out the graphic along with the report, press **<y><Enter>**.

B. To print out only the report without the graphic, press **<Enter>**.

5. The cursor advances to “Confirm: NO”. If everything is acceptable, confirm by pressing **<y><Enter>**.

   Printout of the formal reports on the inclusive sample ID's commences.

18 SYSTEM MENU 1 18-1
18.1 FORMAT DATA FILES 18-1
18.2 SECURITY SYSTEMS: PASSWORD, SIGN ON, OR SET USER PIN 18-2
18.2.1 Password 18-3
18.2.2 Sign ON 18-4
18.2.3 Set User PIN 18-4
18.2.3.1 Add an Operator 18-5
18.2.3.2 Signing On 18-6
18.2.3.3 Delete an Operator 18-7
18.2.3.4 To Edit PIN Information 18-7
18.2.3.5 Forgotten Password 18-8
18.3 DRIVE 18-8
18.4 OPTIONS 18-9
18.5 HOST PARAMETERS 18-11
18.6 LOCATION CODES 18-11
18.7 PANELS 18-12
18.8 REPORT FORMAT 18-13
18.8.1 To Design the Report Format 18-13
18.8.2 Error Code Definition 18-14
18.9 VERSION 18-15

System Menu 1

The “System” menu is used to define all of the operating protocols used by the AMAX 200.

The appearance of the System menu is dependent on whether or not the PIN security system is enabled. If the PIN security system is enabled, the appearance also depends on the assigned security level. Access to some submenus is limited either by Password restrictions (PIN security system not enabled) or by the security level of the signed-on operator (PIN security system enabled). Restricted access submenus are displayed in gray indicating that the associated functions are unavailable.

Because this is a large menu with many submenus, the presentation of the “System” menu has been divided into two sections. The “Parameters” submenu options are discussed in Section 19.
To open the “System” menu, press **<y>** or move the cursor to **“System”** and press **<Enter>**.

Security System Disabled	Security System Enabled		Section
	Access Level 0	**Access Level 1 and 2**	
Format data files	**Format data files**	**Format data files**	18.1
Password	**Sign ON**	**Set User PIN**	18.2
Drive	Drive	**Drive**	18.3
Parameters	Parameters	**Parameters**	19
Options	Options	**Options**	18.4
Host Par.	Host Par.	**Host Par.**	18.5
Location codes	Location codes	**Location codes**	18.6
Panels	Panels	**Panels**	18.7
Report format	Report format	**Report format**	18.8
Version	**Version**	**Version**	18.9

18.1 Format Data Files

Password security system = No restrictions.
PIN security system = 2, 1 and 0.

The “patient archive” can hold up to 1020 data files. A data file includes demographic information and all associated test requisitions and results. A data file may belong to either a patient or a control material. All data files are temporarily stored in the “patient archive”. In addition to being stored in the patient archive, QC results are also stored in the “QC archive”. All patient archive data remains stored until it is deleted. This is usually done on a daily basis but may be done at anytime when the instrument is not processing. All data files in the patient archive are deleted using the “Format Data Files” function. No data is deleted from the QC archive during file formatting.

ATTENTION!
When the data file is formatted, all stored information is deleted. Make sure that there is no further need for this information before formatting the file.

To format the data file:

1. Press **<f>** or move the cursor to **"Format data file"** and press **<Enter>**.
2. Because this is an irretrievable step, confirmation is required. The following dialog window will appear.

```
F O R M A T   P A T I E N T   F I L E
All contained data will be lost ! !
Confirm  :  NO
```

   If all data has been evaluated and/or stored elsewhere, confirm the file deletion with **<y><Enter>**.

   Deny the deletion by pressing **<Enter>**.

The archive must be emptied when all storage space is occupied. No advance warning will be given when the archive is approaching full. Perform the file format as described above.

WARNING!
No more than 1020 entries may be made into the patient archive. System lockup or a runtime error may occur if the entry of more than 1020 files is attempted. Always assure that sufficient archive space is available prior to initiating entry of patient or QC samples. The status footer always contains the number of data files stored in the patient archive.

18.2 Security Systems: Password, Sign ON, or Set User PIN

The AMAX 200 has two security systems.

1. The **Password** Security System protects certain functional areas of the Operating Program. These areas are designed for the use of high level operators or service level personnel and involve either adjustments or settings that are critical to performance or display information that is of no importance to a routine operator. Access to these areas is denied until the correct password is entered. The Password system is a two level system utilizing a laboratory-defined password as the first level and a second level program-defined password intended for use by service personnel.
2. The optional **PIN** Security System works with the QC part of the program and provides an audit trail for certain functions within the QC program. When the PIN System is enabled, the system tracks who is running the instrument when QC is performed and who is editing QC results. When enabled, the PIN system supercedes the password system and, in addition to the QC audit functions, serves as a three level access system that replaces the Password system. Level 0 is equivalent to an Operator in the Password system who does not have the laboratory-defined password. Levels 1 and 2 have the same access as an Operator who is privy to the laboratory-defined password. Level 4 is reserved for service personnel and provides access to those areas protected in the Password system by the service password.

Due consideration should be given prior to enabling the PIN system. To assure PIN security, the program is hidden within the Operating Program and is not easily disabled.

Because the system submenu options are extremely important to the performance of the instrument, access to the submenus is restricted. Access is denied until either the correct password is entered or an operator with a PIN security level greater than zero is signed on.

The submenu that is displayed when the System menu is opened is dependent on whether or not the PIN security system is enabled. If the PIN security system is enabled, the appearance depends on the assigned security level.

Note that when the PIN security system is enabled, entry of a valid PIN is required every time the Operating Program is entered and whenever the program is awakened following screen saver activity. A non-valid PIN entry is always registered as a 0 (zero) level user.

18.2.1 Password

PIN Security system not enabled.

Access to the System submenus is denied until the correct password is entered. With entry of the correct password, all submenus are displayed in black indicating that these areas are available.

Once the correct password has been entered, the "Password" option is used to program a laboratory-defined password.

A. Open the "Password" dialog window by pressing **<p>** or moving the cursor to **"Password"** and pressing **<Enter>**.

```
New password?
NO
```

B. There are two choices:
   a. If you **do not want** to change the password, press **<Enter>**.
   b. If you **do want** to change the password, press **<y><Enter>**.

   Type in the **"new password"** (7 character limit). Confirm with **<Enter>**.

   The new password is now active.

ATTENTION!
Record the password in a safe place. If the password is forgotten, an authorized service representative must be contacted to access the password-protected areas.

It is not possible to totally delete the password option. However, <Enter> may serve as a password thereby eliminating the need to remember any number or letter sequence. To register <Enter> as the new password: In response to the "change password NO" question, press **<y><Enter><Enter>**. <Enter> is now the password. Pressing <Enter> in response to the request for password will provide access to all areas protected by the laboratory-defined password.

The laboratory-defined password will not provide access to those areas restricted for service personnel use.

18.2.2 Sign ON

PIN security system enabled. PIN access level = 0.

Access to all System menu functions except “Format data files” and “Version” is denied to those operators with a security level of 0.

The “Sign ON” submenu is used for logging on a new Operator. Since the primary use of the security system is to supply the QC audit trail, it is important that signing-on be done when a new Operator begins using the instrument.

Press **<s>** or move the cursor to **“Sign ON”** and press **<Enter>**. The “Operator PIN” dialog window will open. The cursor will be flashing in the center of an empty box. Type in your **<PIN number><Enter>**. Note that an alternative way to sign-on is to press **<Alt-F6>**. The “Operator PIN” dialog window will open.

18.2.3 Set User PIN

PIN security system enabled. PIN access level = 2 or 1.

The “Set User PIN” menu is used to add new Operators, remove Operators and to set a new PIN for an Operator who has forgotten their PIN. A signed-on Operator has editing access only for PINs of equal or lessor level. Access is denied to higher access level PINs.

To open the “Set User PIN” dialog window, press **<s>** or move the cursor to **<Set User PIN>** and press **<Enter>**.

[Set User PIN (Your Level: #]

User name	Code	Shift	Level	PIN
Jack Benimble	JB1	1	2	*******
Jack Bequick	JB2	1	1	*******
Peter Principle	Pete	2	2	*******
Oscar Mayer	OHM	3	0	*******
Suzie Succotash	SOS	3	0	*******

Field	Description
Set User PIN (Your Level:#)	The access level of the currently signed-on operator is displayed at the top of the window. The signed-on Operator has full access to his own information area and to unassigned areas. A limited access is granted to the area of other Operators with equal or lower levels access. No access is granted to the area of Operators with a higher level access.
User name	Mandatory entry. User name or other identifier (20 alphanumeric character limit). Upper and lower case letters can be used. This name will be displayed on the “Hallo” greeting screen after entry of the corresponding PIN.
Code	Mandatory entry. Abbreviated unique identifying code that will identify the signed-on Operator. This code will be automatically inserted in the QC audit trail. The Operator’s initials are typically used but any 4-digit alphanumeric entry may be used. For QC audit purposes, the code should be unique. A duplicate entry will not be disallowed.
Shift	Optional entry. A numeric designation designed to signify the

Field	Description
	work shift (5 numeric character limit). Default is 0. Information only field.
Level	Mandatory entry. Security access levels 0, 1 or 2 are the only acceptable entries. Level 0: Operator has access only to functions used during normal operation and QC viewing functions. Access to calibration, programming and QC editing is denied. Level 1 and Level 2: Operators have access to normal operating functions, calibration, programming functions and QC editing functions. Level 2: In addition to those access areas shared with the Level 1 Operator, a Level 2 Operator may edit QC editing done by a Level 1 Operator.
PIN	Mandatory entry. Unique up to 7-digit alphanumeric identifying sign-on code. Duplicate PINs are not allowed.

18.2.3.1 Add an Operator

a. <System><Set User PIN><Enter>. "Set User PIN" dialog window is displayed.

An unlimited number of Operators may be assigned a PIN. Move cursor to an empty position. Use the <←> to move the cursor to the "User name" field.

b. User name: The "User name" entry defines the welcoming name that will be displayed on the PIN entry screen whenever the PIN associated with that name is entered. Type in the **<User name ><Enter>**. (20-character limit).

c. Code: The "Code" entry defines the operator identifier that will be automatically recorded in certain areas of the QC program whenever this Operator is signed-on. The initials of the Operator are typically used as the code. Type in the **<code><Enter>**. (4-character limit).

d. Shift: The "Shift" entry is an additional way to differentiate between Operators. Any up to 4-digit numerical sequence may be entered. **<Shift #><Enter>**.

e. Level: The "Level" entry sets the access level of the assigned Operator. Valid entries are 0, 1 or 2. The currently signed-on Operator can add a new Operator with an equal or lesser access level. **<0, 1** or **2><Enter>**.

(1) **Level 0**: Access is provided only to those areas used during normal operation and QC viewing. No access is provided to calibration, programming, other instrument adjustments or QC editing.

(2) **Level 1**: Level 0 plus access is provided to calibration, programming, other adjustments and QC editing. Access is restricted only in those areas reserved for service level personnel (Level 4).

(3) **Level 2**: Level 1 plus expanded QC editing capability. Access is restricted only in those areas reserved for service level personnel (Level 4). See Chapter 20.3.2.4 and 20.3.2.5.

(4) **Level 4**: "4" is not a valid entry. Level 4 is reserved for service-level personnel. All Level 4 operators use the same PIN entry. A Level 4 operator has access to all operating and QC-edit areas.

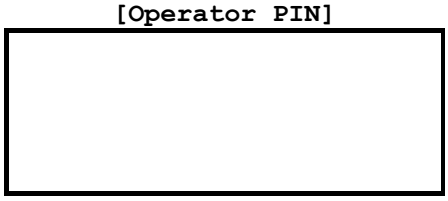
f. PIN: The “PIN” entry is a unique alphanumeric code that associates all of the previously entered information with a specific Operator. The PIN is intended to be known only to the Operator to whom it belongs. PINs are not viewable by other level 1 or 2 Operators. The entry must be unique. An entry that is not unique will result in the message “Invalid” displayed in the PIN field. Up to 7 alphanumeric digits can be used.

   As soon as the cursor enters the PIN field, “Enter your P.I.N.” will be displayed in the help message area at the top of the screen. If the PIN selected is 1-6 digits, type **<selected PIN><Enter>**. If the PIN selected contains 7 digits, type **<selected PIN>**. As soon as either <Enter> or the 7th digit is typed in, the cursor jumps back to the beginning of the PIN field and the top of the screen message display will change to “Reenter your P.I.N.”. Before the PIN assignment process is complete, the selected PIN must be reaffirmed by re-entering the previously entered PIN. **<Retype exactly what was previously entered>**. With entry of the identical PIN, the assignment process is complete and the cursor will advance to the next position. If the re-entry is not identical, the message “error” and “invalid” will be displayed in the PIN field. Try again. The same exact PIN sequence must be entered twice in succession.

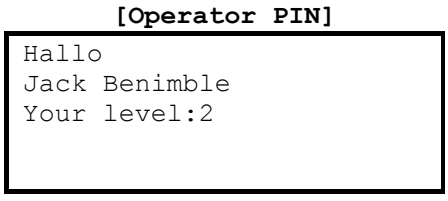
g. After all new Operators have been added, press **<Esc>** to return to the Main Menu.

18.2.3.2 Signing On

Once an Operator has been added to the PIN list, the PIN is used to sign-on whenever the “Operator PIN” dialog window appears.



The cursor will be flashing in the center of an empty box awaiting entry of an Operator PIN. Once the PIN has been entered the “Sign-on greeting” screen is displayed.



The window displays the name and assigned security level as entered in the “User name” and “Level” fields in the “Set User PIN” dialog window. When the greeting disappears, the Operator is signed on.

If an invalid PIN is entered, there will be no greeting. The unknown Operator will automatically be assigned to Level 0. The signed-on unknown Operator will be recorded as “????” in the QC audit trail.

The "Operator PIN" screen will automatically appear whenever the instrument is powered up and when the screen is awakened after the screen saver has been on.

The current Operator can be changed by pressing **<F6>**. The "Operator PIN" screen is displayed awaiting entry of a PIN. A new Operator may sign on during processing by pressing **<F6>** and entering their **<PIN>**.

If the currently signed-on Operator is a Level 0, sign-on can also be done using the Sign ON submenu in the System Menu. **<System><Enter><Sign ON><Enter>**

18.2.3.3 Delete an Operator

An Operator can only be deleted by an Operator with an equal or higher security access level.

<System><Set User PIN><Enter>. "Set User PIN" dialog window is displayed.

As the cursor is moved down the listing, the help area at the top of the screen will display the options available. If the security level of the signed-on Operator is equal to or greater than the level of the Operator at the cursor position, "F9:Delete user" will be displayed in the help area. If the cursor-position Operator has a higher security level than the signed-on Operator, the entire information line will be highlighted and the help area display will say, "You have no access to this entry".

a. Move cursor to the Operator to be deleted.

b. Press **<F9>**.

c. Press **<Esc>** to complete the deletion.

18.2.3.4 To Edit PIN Information

The PIN information for a level 1 or 2 Operator can only be edited by that Operator when that Operator is signed on. No information for any other Operator can be edited. Because a 0 level Operator does not have access to the "Set User PIN" screen, the information for a 0 level Operator cannot be edited. To change PIN information for a 0 level Operator, the Operator must be deleted (18.2.3.3) and the new information entered as described in 18.2.3.1.

To edit PIN information: **<System><Set User PIN><Enter>**. "Set User PIN" dialog window is displayed.

a. Move cursor down to the position of the signed-on Operator.

b. Using the <left or right arrow keys>, move the cursor to the field to be edited. Make changes as appropriate. The User name, Code, Shift and PIN can be edited with no restrictions. The access level can only be changed to a lesser level.

c. All changes must be confirmed by entry of the PIN. **<PIN><Enter>**. If the PIN number entered has not changed, the editing process is completed. If the PIN has changed, the PIN must then be re-entered to confirm the change.

18.2.3.5 Forgotten Password

Operators will occasionally forget their password.

a. Sign on another Operator with an equal or greater access level than the Operator who has forgotten their password.

b. Move the cursor to the forgotten Operator's information line.

c. Press **<F9>** to delete.

d. To gain full access to the line, press **<Arrow up or down>** once to leave the line. Using the **<opposite arrow key>**, return to the line and re-enter all information as described in 18.2.3.1. An alternative is to **<Esc>** the window and re-enter.

18.3 Drive

Password security system = Laboratory-defined password.
PIN security system = 2 or 1.

The default patient file storage area is on the hard disc "c:\" in the directory "AMAXD\". A different drive and/or directory may be defined using the "Drive" option.

ATTENTION!
A new directory must be made prior to defining a new directory for data storage. This cannot be done within the AMAX 200 Operating Program. Using the "End" menu, exit to DOS and make a new directory.

Example: **To make a new directory** named "amax1\" on drive a:\

1. **<End><Enter><Yes><Enter>**

   At exit from the operating program, the currently defined drive and directory are displayed. For example: c:\AMAX

2. If the new directory is to be created on drive A, insert a 1.44 KB/HD floppy disc into drive A.

   a. If the current drive is anything other than "c": **<c:><Enter>**. The drive will change to c:\

   b. At c:\amax change to the root directory: **<cd..><Enter>**

   c. At c:\ change to the DOS directory: **<cd><space><dos><Enter>**

   d. At c:\dos create a new directory: **<md><space><a:\amax1><Enter>**

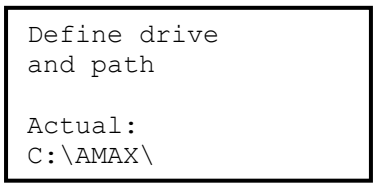
   e. At c:\dos change to root directory: **<cd..><Enter>**

   f. At c:\ change back to current directory: **<cd><Space><c:\amax><Enter>**

   g. At c:\amax return to the AMAX 200 operating program: **<a><Enter>**

To change the drive and/or directory where data will be stored:

1. With the expanded "System" menu available (Password security system) or a level 1 or 2 Operator signed-on (PIN security system), enter **<d>** or move the cursor to "**Drive**" and press **<Enter>**. The "Drive" dialog window will open.



Current drive and directory

2. Enter the new drive and directory. For example: **<a:\amax1\><Enter>**

The new directory entry must end with " \ ". Invalid path instructions are not accepted.

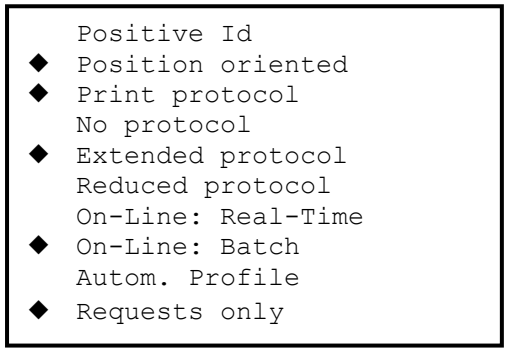
If this is not a newly defined directory and already contains patient files, the operating program will automatically load all the current standard curves into the new directory.

18.4 Options

Password security system = Laboratory-defined password.
PIN security system = 2 or 1.

The "Options" settings control how the system identifies samples and how the results are handled.

With the expanded "System" menu available (Password security system) or a level 1 or 2 Operator signed-on (PIN security system), press **<o>** or move the cursor to "**Options**" and press **<Enter>**. The "Options" dialog window opens.



Current selections are marked with ◆

These are all paired options.

- Sample identification may either be “Positive Id” or “Position oriented”
- Real-time printout may either be “Print protocol” or “No protocol”
- There is no difference in real-time reduced and extended printouts.
- On-line transfer of results may either be “On-Line: Real-Time” or “On-Line-Batch”
- Tests may be requisitioned either as an “Automatic profile” or as “Requests only”

To select an option: move cursor to the **<desired option>** and press **<Enter>**. The opposing option will automatically deselect.

System Options	
Option	**Function**
Positive Id	Samples are identified and registered with the integrated barcode scanner during routine testing.
Position oriented	Samples are identified and position registered using keyboard entry or off-line barcode scanner.
Print protocol	Results are printed in real-time as each sample is completed.
No protocol	Results are not printed in real-time. Real-time results observed in Overview, Results. Results stored in protocol.dat file. May be printed through DOS.
Extended protocol	Real-time 3-line result printout with a separating line between each sample.
Reduced protocol	Real-time 3-line result printout with a separating line between each sample.
On-Line: Real-Time	Sample ID request from the LIS occurs sample by sample as entered in the LIS.
On-Line: Batch	Sample ID request from the LIS occurs through the "Import" command. Results are transmitted to the LIS using the "Export" command.
Autom. Profile	Active with Positive Id only. All tests comprising the active Test Group are run on all samples.
Requests only	Only requested tests are run on all samples. When used in conjunction with Positive Id, is only effective with interface to a host computer. With Positive Id on, using default barcode programming, if the scanner is unable to read a barcode, all tests in the Test Group will be run on that sample and ID = unknown XXX will be allocated (XXX = consecutive number)

18.5 Host Parameters

Password security system = Laboratory-defined password.
PIN security system = 2 or 1.

The communication parameters between the Host and the AMAX 200 are defined using the "Host Parameters" option.

The AMAX 200 is capable of either monodirectional or bidirectional data transmission. Unless otherwise informed, the instrument is shipped ready for bidirectional transfer.

The dialog window that opens when "Host Parameter" is selected depends on whether a monodirectional or bidirectional interface is installed.

With a **bidirectional interface** the “Host Parameter” dialog window opens:

[Host Parameters]

```
Inst. ID      :  AMAX1
Master/Slave  :  MASTER
TC-str  No    :  2
ASCII chr     :  $OD
                 $OA
baud rate     :  19200
data bits     :  8
stop bits     :  1
parity        :  NO parity
```

Enter parameters as appropriate. Exit screen with **<Esc>**. Reboot PC to activate the new parameter definitions. More information on the bidirectional interface may be found in the Appendix.

With a **monodirectional interface** the “On-line” dialog window opens:

```
Data bits      :        7
Stop bits      :        2
Parity         :        EVEN
Errors inc.    :        NO
Instr. No.     :        1
```

Enter parameters as appropriate. Exit screen with **<Esc>**. Reboot PC to activate the new parameter definitions.

18.6 Location Codes

Password security system = Laboratory-defined password.
PIN security system = 2 or 1.

Use of the “Locations” option simplifies patient location information entry. In addition, results may be sorted and printed according to the defined location.

The instrument identifies the location using assigned identifier codes. Up to 32 different locations may be coded.

To open the “Location codes” dialog window: With the expanded “System” menu available, press **<l>** or move the cursor to **“Location codes”** and press **<Enter>**.

[Location codes]

```
ER  : Emergency Room            :
ICU : Intensive Care Unit       :
MH  : Mercy Hospital            :
OP  : Out Patient               :
PED : Pediatrics                :
QC  : Quality Control           :
    :                           :
    :                           :
    :                           :
    :                           :
```

1. In the first column, type the **"desired code"** (6-character limit) followed by **<Enter>**.
2. In the second column, type the "**full name**" (20 character limit) for the location followed by **<Enter>**.
3. After all locations have been coded, exit the window with **<Esc>**.

   If the codes have been entered with no empty lines between entries, the listing will be sorted and stored alphabetically.

   Once location codes are defined, when any dialog window has a "Loc." field, the appropriate location may be entered either by typing in the code or by opening the "Location codes" window using **<.>** or **<,><Enter>** and then making the appropriate selection.

18.7 Panels

Password security system = Laboratory-defined password.
PIN security system = 2 or 1.

Use of the "Panels" option simplifies test requisitioning. A defined panel is a specific grouping of tests that are requested as a unit. A panel may contain from 1 to 8 tests.

1. With the "System" menu open, press **<n>** or move the cursor to "**Panels**" and press **<Enter>**. The "Panels" dialog window will open.

[Panels]

No.	Tests		
1	PT	PTT	
2	PT	PTT	FIB
3	PTT	AT	HEP
4	F8	F9	
5			
6			
7			
8			
9			

2. Add tests by moving the cursor (↑ and ↓ keys) to a panel number and either type in the **<test code>** or **<test number>** followed by **<Enter>**.

   If you don't know the exact code or test number, press **<+><Enter>** to bring up the **"Test list"**. Move the cursor to the **<desired test>** and press **<Enter>**.

3. Delete tests from an already defined panel by moving the cursor to that panel and then moving the cursor (→ and ← keys) to the test to be removed. Press **<space><Enter>** to delete the test.

18.8 Report Format

Password system = Laboratory-defined password.
PIN security system enabled. PIN access level = 2 or 1.

The "Report format" option is used to customize the appearance of the formal report to the needs of each laboratory.

An 8½" (216 mm) wide sheet of paper is divided into 80 columns. Each column represents approximately 0.11 inches (2.7 mm). An 11" (279 mm) long sheet of paper is divided into 66 lines. A line represents approximately 0.17 inches (4.23 mm). The report may be formatted to look anyway you want it to by specifying the line and column location. The size of the type for each item may also be specified.

18.8.1 To Design the Report Format

A. With the expanded "System" menu available, press **<e>** or move the cursor to **"Report format"** and press **<Enter>**. The "Report format" dialog window opens.

[Report format]

Ident.S.: 12 **Res. N.:**23 **Res. S.:**4 **Res. E.:**50

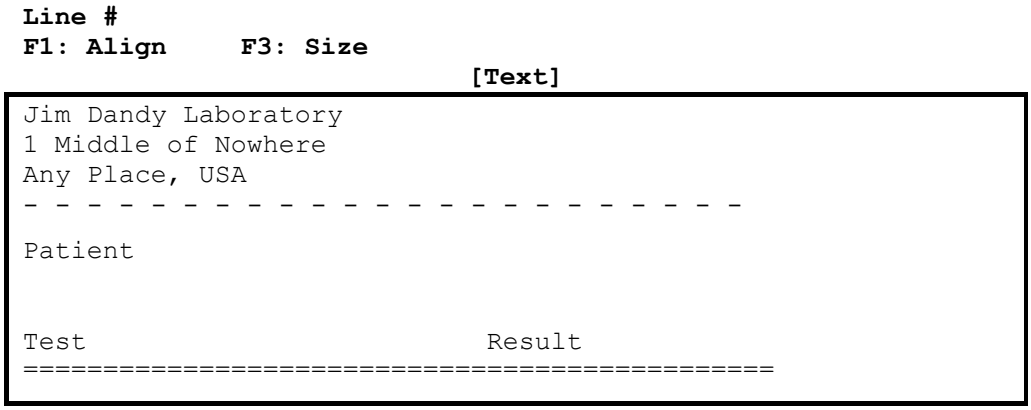
	Line	**Col**	**Chr**	**Desc.**
Seq. number	0	0	S	
Identification	1	1	N	Patient ID:
Name	3	1	N	Patient Name:
Location	4	40	N	Location:
Note	7	1	N	Comments:
Reg. date	0	0	N	Request date:
Date of print	6	65	S	Print date:
Test code	0	0	N	
Test name	1	2	N	
Result (1)	1	40	N	
Meas. Unit (1)	1	50	S	Units:
Normal range (1)	1	28	S	Normal:
Result (2)	2	40	N	
Meas. unit (2)	2	50	S	Units:
Normal range (2)	2	28	S	Normal:
Result (3)	3	40	N	
Meas. unit (3)	3	50	S	Units:
Normal range (3)	3	28	S	Normal:
Error message	1	62	N	

Report Form	
Field	**Setting Definition**
Ident. S.	Defines the first line for patient identification. For example: 12 means that patient identification information starts in the twelfth row.
Res. N.	Defines the first line for test result printout.
Res. S.	Defines the number of lines each result is to occupy (range = 1 to 4). This setting determines the density of the report. It also determines how many test results may be printed on one page.

Res. E.	Defines the last line for test result printout. The lower part of the report may be reserved for comments and/or signature.
Line	Defines the line on which the field will be printed.
Col	Defines the in column which the results will be printed. The program automatically adjusts column width to compensate for differences in typeface.
Chr	Defines the character face that will be used to print the field. Enter either the face codes (N = normal; S = compressed; L = large) or press <F3> to select a face.
Desc	Defines a descriptive text that may precede any field.

B. Make value entries as appropriate. If you don't want certain fields to appear on the formal report, type “0” (zero) into both line and column for that field.

C. A header may be designed to personalize the report. With the “Report format” dialog window open, press **<F1>** to open the “Text” dialog window.



a. Type in the desired text line by line. The line number is displayed at the top of the window. Use the line count to determine exactly where to position text in relationship to the defined field data.

b. To determine the character size, move the cursor to the appropriate line. Press **<F3>** and select <**Normal>**, **<Small>** or **<Large>**.

c. To determine the position on the page, move the cursor to the appropriate line. Press **<F1>** and select **<Left>, <Center>** or **<Right>**.

18.8.2 Error Code Definition

Seven different error conditions are automatically recognized by the operating program. The message to be printed in place of a result when any of these errors occur may be defined. In addition to the 7 instrument codes (0 through 6), there are 3 additional codes (7 through 9) that may be defined and used to mark error conditions.

17.2

Press **<F2>** to open the "Error messages" dialog window.

[Error messages]

Code	Meaning	Message
0	NOT PROCESSED	Pending
1	DUPLICATE ERROR	Duplicate error
2	CALC. ERROR	Calculation error
3	NOT CLOTTED	No clot detected
4	MISSING SAMPLE	Insufficient sample
5	TO REPEAT	To be repeated
6	BARCODE ERROR	Barcode discrepancy
7	free	Clot in sample
8	free	Transport delay
9	free	Hemolyzed

Type in the message that is to be printed in the "Message" column.

When one of the automatically recognized error codes (0 through 6) occurs or if the results are edited by insertion of a defined error code (7 - 9):

- The result will not be printed.
- The result will not be stored.
- The error code is stored.
- The defined error message is printed.

18.9 Version

Password security system = No restrictions.
PIN security system = 2, 1 or 0.

The "Version" option is a display-only window that shows the currently installed versions of the different modules and the PC software. This may be a window that you will be asked to open when troubleshooting with Sigma Diagnostics Technical Service.

With the expanded "System" menu open, press **<v>** or move the cursor to **"Version"** and press **<Enter>**. The "Version" display window opens.

[Version]

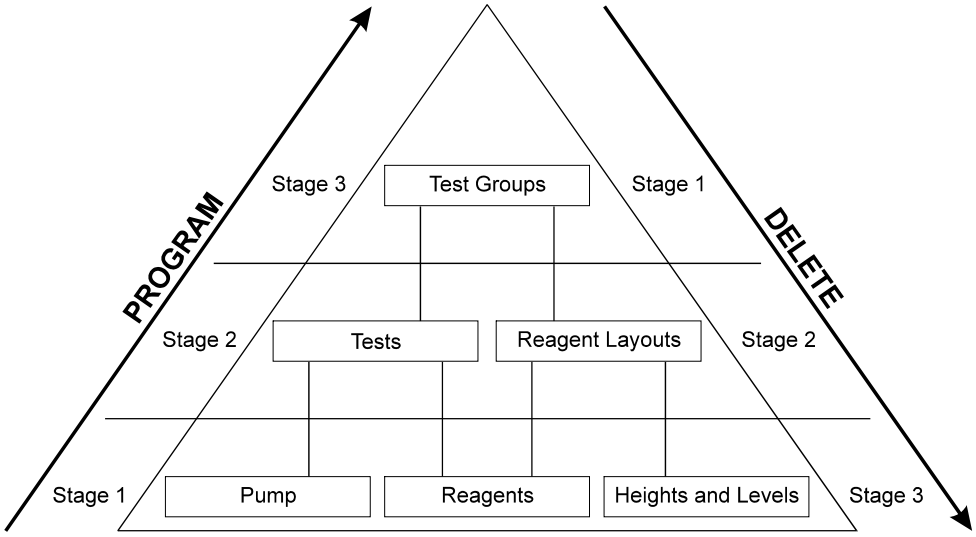
```
PC-Software:3.1.1A  26.11.98
   AMAX.EXE         3.1  26.11.98
   IOAMAX.DLL       3.1  25.08.98
   HOST.DLL         1.4  20.05.96
   PHOTO.BINPHM     1.9  16.02.96
Modules
   Robot       LRB  3.5  29.11.94
   Cuvettes    KMA  2.4  24.05.95
   Wheel       RPB  2.4  05.01.95
   Cooling     WKL  2.2  28.09.95
   Pump        DOS  1.2  14.03.95
   Opt. Meas.  HP8  1.1  15.09.94
   Mech. Meas. KMM  4.1  21.07.93
```

19 SYSTEM MENU 2 - PARAMETERS.....19-1
19.1 TEST GROUPS..... 19-2
19.1.1 To Define or Modify a Test Group..... 19-3
19.1.2 To Delete a Defined Test Group..... 19-5
19.2 TESTS..... 19-5
19.2.1 To Define a New Test..... 19-6
19.2.1.1 Description..... 19-7
19.2.1.2 Calibration..... 19-7
19.2.1.3 Procedure..... 19-10
19.2.1.4 Data Reduction..... 19-11
19.2.1.5 Statistics..... 19-12
19.2.2 Undo Test Parameter Definition..... 19-13
19.2.3 Exiting Test Parameter Definition..... 19-13
19.2.4 Saving Test Parameter Definition..... 19-13
19.2.5 Copy Test Parameter Definition from One Test to Another..... 19-14
19.2.6 To Delete a Test from the Test List..... 19-14
19.2.7 Predilution Mode..... 19-14
19.2.8 Derived Fibrinogen..... 19-15
19.3 REAGENT LAYOUT..... 19-16
19.3.1 To Define or Modify a Reagent Layout..... 19-17
19.3.2 To Delete a Previously Defined Layout..... 19-18
19.4 REAGENT..... 19-18
19.4.1 To Define a New Reagent or Modify a Previously Defined Reagent..... 19-19
19.4.2 To Delete a Reagent..... 19-20
19.5 LEVELS..... 19-20
19.5.1 Diameter..... 19-21
19.5.2 Bottom Levels..... 19-22
19.5.3 Maximum Level..... 19-23
19.5.4 Predilution Levels..... 19-23
19.6 PUMP..... 19-24
19.7 MEASURING MODE..... 19-25
19.8 TEMPERATURE..... 19-28
19.9 BACK UP..... 19-29
19.10 RESTORE..... 19-29
19.10.1 To Restore a Back up File..... 19-30
19.10.2 To Activate the Back up Parameters..... 19-31

The “System” menu is used to define all of the operating protocols used by the AMAX 200. Because this is a large menu with many submenus, the presentation of the “System” menu has been divided into two sections. Section 18 discussed all options on the “System” menu except “Parameters”. The “Parameters” section defines all the parameters used in actual test performance.

Because the parameter definitions are critical to test performance, access is limited either by Password restrictions (PIN security system not enabled) or by the security access of the signed-on operator (PIN security system enabled). Restricted access submenus are displayed in gray indicating that the associated functions are unavailable.

Many things have to happen in a coordinated fashion to produce a test result. One thing has to take place before another can happen. The test parameters are structured like a pyramid. To build a pyramid, you start at the bottom and work up. To destroy a pyramid, you start at the top and work down.



The Test Group is the key for all testing on the AMAX 200. A Test Group is made up of tests that use specific reagents. Before a Test Group may be defined, the tests comprising that group have to be defined. The instrument has to know where to find the appropriate reagent. The reagent(s) location has to be defined. Before you may define a test or position the reagent(s), you have to define each reagent that will be used. Other considerations include the delivery of reagent to the testing point and the monitoring of reagent usage.

Before a test may be deleted, it has to be removed from any Test Groups to which it is assigned. After this step, the test may be deleted and the reagent(s) removed from the positioning map if they are not used for any other test.

When the PIN security system is enabled, the “Parameters” area is available to level 1 and 2 Operators. Certain areas within the “Parameters” submenu are further protected with access limited to PIN level 4 (authorized service personnel).

When the PIN system is not enabled, the “Parameters” area is located in the laboratory-defined password protected area of the “System” menu. Certain areas within the “Parameters” submenu are protected with an additional service password. To open the “Parameters” submenu: With the expanded “System” menu open, press **<r>** or move the cursor to **“Parameters”** and press **<Enter>**.

Test groups	Section 19.1
Tests	Section 19.2
Reagent layout	Section 19.3
Reagent	Section 19.4
Levels	Section 19.5
Pump	Section 19.6
Meas. Mode	Section 19.7
Temperature	Section 19.8
Back up	Section 19.9
Restore	Section 19.10

19.1 Test Groups

Password security system = Laboratory-defined password.
PIN security system = 2 or 1.

All testing on the AMAX 200 is done in Test Groups. A Test Group is a defined group of from 1 to 12 tests in normal operating mode or 1 to 8 in Quick Start operating mode. Any combination of from 1 to 12 tests (or 1 to 8 in Quick Start) within the group may be run simultaneously. Each test within the group may be run either singly or in duplicate.

Before defining a Test Group, the component test(s), the Reagent Layout (reagent positioning), and the reagents must have already been defined. Refer to Sections 19.2 (Tests), 19.3 (Reagent layout) and 19.4 (Reagent).

19.2
19.3.1
19.4.1

To open the “Test groups” selection window, press **<g>** or move the cursor to **“Test groups”** and press **<Enter>**.

[Test groups]

```
Group
Routine
Quick Start
PT
PT/PTT
PTT/AT3
FIB
INFAC
EXFAC
```

1. To define a new Test Group, move the cursor to an **empty position** and press **<Enter>**.
2. To modify or delete a Test Group, move the cursor to the **appropriate group** and press **<Enter>**.

The “Test Group” definition dialog window will open.

F1:Reagent Layout or Test list F9:Delete F10:Undo

```
            [Test group]
           Name:  Routine
     Batch size:  4
 Reagent layout:  ROUTINE
      Tests -- Replicate
   1: PT       Single
   2: PTT      Single
   3: FIB      Duplicate
   4:
   5:
   6:
   7:
   8:
   9:
   10:
   11:
   12:
```

Field	Definition
Name	Name assigned to the Test Group. (Character limit = 20)
Batch size	Number of samples to be run in batch series (1 - 12). The order of testing is prioritized by the instrument according to the total sum of all the incubation times plus the Max Time (or Max time 2) setting. The tests with the longest total processing time will be processed last in the batch series.
Reagent layout	Name of the layout defining the positioning of the reagents assigned to the Test Group. (Character limit = 20)
Tests	Test code name
Replicate	Number of times each test will be sampled. Single or duplicate.

19.1.1 To Define or Modify a Test Group

A. Type in a descriptive name that will identify the Test Group (character limit = 20). Complete with **<Enter>**.

B. Type in the number of samples to be run as a batch. This number may range from 1 to 12. With a setting of 1, the instrument runs all tests on each sample before going to the next sample. With a setting of 12, the instrument runs all tests requested on a group of 12 samples before moving on to the next group of 12 samples. The number selected affects throughput and Stat turn-around time. The usual number selected is somewhere between 4 and 12. The decision is dependent on how quickly all test results on the average sample will be needed and how quickly Stats must be processed. The closer the number is to 1, the quicker all results on each sample will be available; but, it will take longer to process all samples.

   The test processing order is dependent on the total programmed time (incubation times plus Max Time (or Max Time 2) for each test within the Test Group.

C. Assign a Reagent Layout to be used with the Test Group. All reagents required to do all tests in the Test Group must be included in the Reagent Layout.

19.3

With the cursor at the Reagent Layout entry position, press **<F1:Reagent layout>** to open the "Reagent Layout" selection window. This listing shows all previously defined Reagent Layouts.

[Reagent Layout]

```
Layout
Routine
Quick Start
PTT/AT3/HEP
PT-M/PTT-O
INFAC
EXFAC
```

Move the cursor to the desired Reagent Layout and press **<Enter>**.

That layout will then be assigned to the Test Group. The Reagent Layout assignment may be changed by following the same procedure.

There are several considerations when selecting a Reagent Layout. All the reagents that are used by the tests within the group must be assigned to the layout. The instrument will look for the presence of each of those reagents every time the Test Group is activated. In some circumstances (Positive Id on), processing will not begin until an adequate volume of each reagent is present. In any circumstance, the search for each reagent takes a certain amount of time. Having extraneous reagents assigned to a Test Group will slow the start of processing. If Stats are to be run using the Test Group, then the selected Reagent layout must include defined Stat positions.

D. Assign the tests to be included in the Test Group. All tests must have been previously defined.

19.2

Tests may be added by entering either the test code name or number. To bring up a listing of the defined tests, press **<F1:Test list>** or **<+><Enter>**.

[Test List]

```
PT-O      Pro Time - Optical
PT-M      Pro Time - Mechanical
PTT-O     APTT
FIB       Fibrinogen (Clauss)
AT3       AT III
HEP       Heparin
F8        Factor VIII
```

Move the cursor to the first test to be included in the Test Group and press **<Enter>**. The selected test will be inserted into the Test Group display. Enter **<S>** (single sampling) or **<D>** (duplicate sampling) in the Replicate column.

Continue adding tests until all tests comprising the Test Group have been added.

E. To **remove a test** from a Test Group, move the cursor to the test to be removed and press **<Space><Enter>**.

F. If you decide at this point not to make any modifications, press **<F10>**. The Test Group will revert to its previous definition. Note that "Undo" (<F10>) means to discontinue any modifications and that "Delete" (<F9>) means to delete the entire Test Group.

19.1.2 To Delete a Defined Test Group

Open the "Test groups" selection window:

(<System><Password><Parameters><Test groups>). Move the cursor to the Test Group to be deleted. Press **<Enter>**. With the "Test group" dialog window open, press **<F9:Delete>**. You will be asked to confirm the deletion.

```
Delete Test Group
Do you want to delete ? NO
```

Press **<y><Enter>** to confirm deletion. Press **<Enter>** to deny deletion.

19.2 Tests

Password security system = Laboratory-defined password.
PIN security system = 2 or 1.

The "Tests" submenu item is used to define all operating parameters pertinent to each test. The test parameters tell the instrument exactly how to do the test, what reagent(s) to use, how to calculate the result, how to report the result and how to handle any associated patient statistics.

Up to 32 tests may be defined. Test position number 33 is reserved for Derived Fibrinogen which is calculated using the turbidity developed during optically measured prothrombin time. If Derived Fibrinogen is to be measured, optically measured PT must be programmed as test number 1.

Any associated reagents must have been previously defined.

19.4

The Measuring Mode to be used must be included in the listing of available modes.

19.7

To open the “Test list”:

<System><Parameters> Press **<t>** or move the cursor to **“Tests”** and press **<Enter>**.

F1: Print test list F9: Reset counter

[Test List]

	Test	Code	Count since 06/08/99
1	Pro Time-Optical	PT-O	174
2	Pro Time-Mechanical	PT-M	3
3	APTT	PTT	97
4	Fibrinogen (Clauss)	FIB-O	85
5	AT III	AT3	21
6	Heparin (chromogenic)	HEP	5
7	Factor VIII	F8	6
8	Factor IX	F9	2
9			
10			
.			
.			
33	Derived Fibrinogen	DF	

A listing of all programmed tests may be printed by pressing **<F1:Print test list>**.

The numbers to the left of each position are instrument-assigned Test Numbers. This number is always recognized as referring to the test defined in that position. These numbers or the assigned code may be entered in other window where insertion of test is required.

The numbers to the right of each test code are the numbers of tests that have been performed since the date displayed at the column top. The counters for all tests may be reset by pressing **<F9>**. Test count cannot be reset individually.

19.2.1 To Define a New Test

A. Move the cursor to an **empty position** and press **<Enter>**. To modify an already defined test, move the cursor to the **test you wish to modify** and press **<Enter>**. The “Test parameters” dialog window opens.

F7:Copy F9:Delete F10:Undo

[Test Parameters]

Seq. number :7

Name:Factor VIII
Code:F8

Edit	Status	Section	Content/Error
No	OK	Description	
No	OK	Calibration	Curve
No	OK	Procedure	Optical, normal
No	OK	Data reduction	Curve, Time val.
No	OK	Statistics	

When this window opens, the sequence number selected in the Test List will be displayed. The parameters for each test are divided into five sections.

Each section defines specific functions within the test. Each section has a dialog sub-window. All sections must be completed.

19.2.1.1 Description

When the window opens, the cursor will be positioned on the "Description" field. Press **<Enter>** to open the "Description" sub-window.

[Description]

```
Name  :Factor VIII

Code  :F8
```

a. Type in the long name for the test (Character limit = 30). Complete with **<Enter>**. The long name will be printed in the patient report. It will also be displayed in the Test List.

b. Type in a unique code name for the test (Character limit = 6). Complete with **<Enter>**. Use a combination that will readily identify the encoded test. The Test Code may be entered in any other window where insertion of a test is required. The test code is used to identify tests in the real-time result list.

   Close the window by pressing **<Esc>**. The "Test parameters" window will return to the screen.

19.2.1.2 Calibration

Move the cursor to the "Calibration" section and press **<Enter>**. The "Calibration" sub-window opens.

[Calibration]

```
Curve type :2          Curve:     Value     Sec/mE
Dilution r :5                     96          34.7
Max. Value :192                   48          38
Standard   :0                     24          42.1
ISI-Factor :0                     12          46.5
Max. CV    :20                    6           51.2
Max Time   :75                    0           0
Max Time 2 :0                     0           0
Delay      :25                    0           0
Impulse t. :0                     r:-0.9998483
```

Test Parameters - Calibration	
Parameter	**Setting Definition**
Curve type	Code number for the type of curve used to calculate the results. If no curve is used, enter "0". 0 = reciprocal/linear plot; point to point calculation 1 = reciprocal/linear plot; linear regression best fit calculation 2 = log/log plot; point to point calculation 3 = log/log plot; linear regression best fit calculation 4 = linear/linear plot; point to point calculation 5 = linear/linear plot; linear regression best fit calculation 6 = log/linear plot; point to point calculation 7 = log/linear plot; linear regression best fit calculation 8 = linear/log plot; point to point calculation 9 = linear/log plot; linear regression best fit calculation

Test Parameters - Calibration	
Parameter	**Setting Definition**
Dilution r	Dilution on which the curve is based. Serves as a signal to the instrument for redilution when measured time is above or below the span of the curve. Any ratio from 0 to 100 may be entered. Dilutions from 1:2 to 1:20 are usually done using the normal dilution mode. Dilutions higher than 1:20 are best done using the predilution mode. See 19.2.7, Predilution Mode. With a dilution ratio set to 0, redilution will not be done. With a dilution ratio > 2, samples yielding a measuring time either above or below the curve limits will be automatically rediluted using a higher or lower dilution as appropriate. Samples with a measured timed shorter than Standard are rediluted by a factor of 2, e.g., primary dilution of 1:10 will be rediluted and rerun at a dilution of 1:20. With an even numbered primary dilution (2, 4, 6, etc.), redilution of samples with a measured time longer than the last standard is by a factor of ½, e.g., primary dilution of 1:10 will be rediluted and rerun at a dilution of 1:5. With an odd number primary dilution (3, 5, 7, etc.), redilution of samples with a measured time longer than the last standard is by a factor of ½ rounded down to a whole number, e.g., primary dilution of 1:7 will be rediluted and rerun at a dilution of 1:3. Use only with inversely proportional reactions. Redilution is not functional in the chromogenic measuring mode.
Max. value	Maximum reportable limit of calculated values. Values above the limit will be reported as > maximum value setting. Refers only to calculated values. The number of digits entered at Max. Value determines the number of decimal digits printed in the result. >100 = no decimal digit; 10 - 99 = 1 decimal digit; <10 = 2 decimal digits. Regardless of the setting for Max. Value, any calculated result which is <1 will be reported with two decimal digits. For example: Max. Value is set at 200. All results >1% will be reported with no decimal digits but results <1% will be reported with two decimal digits.
Standard	Time value used for the calculation of Ratio and INR. Geometric mean is recommended for INR calculation. May be used to calculate ratio between any observed value and a standard value.
ISI-Factor	Enter assigned ISI value for the thromboplastin reagent being used for INR calculation. Enter 1 for ratio determination.
Max. CV	Maximum acceptable variation between duplicate determinations. Example: For $\pm$ 5% agreement between duplicates, enter 5. Any samples not meeting this criterion will be automatically repeated. How this parameter is set is dependent on the purpose for testing in duplicate. If the measured difference between duplicate measurements is to be used to decide whether to release the patient results, the parameter is usually set to twice the analytic CV. Twice the analytic CV generally represents action limits because this approximates the 95% confidence limits. Because the tests are run in duplicate, the size of the error is greater than for a single test because there is double the opportunity for error to occur. The analytic CV is used when the values are used to estimate the analytic error of the method and

Test Parameters - Calibration	
Parameter	**Setting Definition**
	is being used for quality control purposes. This serves as an alternative or supplement to determining the analytic CV from a single control material.
Max Time	Maximum measuring time in seconds. Any sample not clotted within this time interval will be automatically repeated according to the Max Time 2 setting. Time entered influences throughput. Enter a time that the majority of results will be under.
Max Time 2	Maximum measuring time in seconds for automatic repeat of any sample not clotted by the end of Max Time. Entry of 0 (zero) prevents automatic repeat but does not inhibit the automatic redilution function when the dilution ratio is set to > 2.
Delay	Delay time before measurement begins. For most tests, allow a minimum of 3 seconds for any turbulence created by reagent addition to subside and for the ball to stabilize.
Impulse t	Only active in mechanical measurement mode. Time before constant rotation stops and interval rotation begins. See Section 11.1, Measurement Principles, Mechanical Measurement.
Curve: Value/Sec/mE	Value column = % Activity or concentration values. The highest % Activity or concentration must be standard 1. “0” cannot be entered as a value. Sec/mE column = Time or absorbance value which corresponds to the opposite % Activity or concentration value. To avoid a programming error, each value in column 1 must always be opposed by a Sec/mE in column 2.
r	Instrument calculated correlation coefficient of the calibration curve.

a. Enter the calibration parameters as defined by the reagent manufacturer's application for the AMAX 200.

b. When all parameters have been entered, press **<Esc>** to return to the “Test parameters” dialog window. Calibration performance is discussed in Section 22.

22

19.2.1.3 Procedure

Move the cursor to the “Procedure” section and press **<Enter>**.

A “Procedure” sub-window opens. The sub-window displayed is dependent on the pipette mode selected.

- Pipet Mode 0 (“Normal” pipetting mode):

```
   Meas.m. :E            Pipet mode   :0
                         Mix volume   :0
   Sample     Reagent               Volume   Incubation   Next step
   8          Imidazole Buffer      32       30           S1
S1  Reag 2    Factor IX Deficient   40       30           S2
S2  Reag 3    APTT                  40       180          S4
S3  Reag 4
S4  Startr    Calcium Chloride      40
```

- Pipet Mode 1 (“One-step/No Incubation” mode):

```
   Meas.m:E                 Pipet mode    :1
                            Mix Volume    :0
   Sample     Reagent              Volume
   25         ThromboMAX             50
```

- Pipet Mode 2 (“Two-step or Reverse Pipetting” mode):

```
   Meas.m.:E                Pipet mode    :2
                            Mix volume    :0
   Sample     Reagent              Volume    Incubation
              ThromboMAX             50         30
   25
```

Test Parameters - Procedure	
Parameter	**Setting Definition**
Meas.m.	Measuring mode. 10 measuring modes are available for use at any given time. See Section 19.7. M = Mechanical measurement A - I = Optical measurement With the cursor in the “Meas.m.” field, press <F1:Meas. mode> to display listing of selectable modes.
Pipet mode	0 = Normal pipetting procedure: Sample and reagents are pipetted into cuvettes in the incubation rail. Before adding the Start Reagent, the cuvette is transferred into the measuring well. 1 = One-Step procedure: An empty cuvette is transferred to the measuring area. Then sample and one reagent are picked up in one single step and dispensed directly into the empty cuvette. 2 = Two-Step procedure: Reagent is aspirated and dispensed into multiple cuvettes. After an incubation period, the cuvette is transferred to the measuring area where sample and a second reagent (if appropriate) are added to start the measurement.
Mix volume	Mixing volume of the sample. The programmed mixing volume (0 -400 µL) is aspirated from the sample and dispensed back into the sample container. After this step, the programmed sample volume is pipetted. Mixing should always be used with whole blood samples.

Test Parameters - Procedure	
Parameter	**Setting Definition**
Sample	Primary sample volume in µL (Range = 5 – 500 µL). Must be an even number and be greater than 3 when divided by 2 (≥ 6) if auto-dilution of samples exceeding Standard 1 is desired. For predilution procedures, enter volume of diluted sample to add. If the volume programmed is < 50 µL and sample is being dispensed without reagent in the same pipetting step, the volume aspirated is the programmed volume + 20 µL. If the volume programmed is ≥ 50 µL, the volume aspirated is the programmed volume. If sample is being dispensed with a reagent, reagent is always aspirated first followed by sample. The sample volume aspirated is the programmed volume. The volume dispensed is always the programmed volume.
Reagent	Name of the reagent to use. Press <F1> to display the "Reagent list". Add reagents in the appropriate sequence. Last reagent added must be in S4 position.
Volume	Reagent volume in µL. (Range = 5 - 400 µL). Minimum total reaction volume for a mechanical measurement = ≥ 75 µL. Minimum total reaction volume for optical measurement = ≥ 150 µL. Maximum total reaction volume = 600 µL. A procedural error will occur if the final total volume is not above the minimum reaction volume specification. If the reagent volume programmed is < 50 µL, the volume aspirated is the programmed volume + 5 µL. If the volume programmed is ≥ 50 µL, the volume aspirated is the programmed volume. The volume dispensed is always the programmed volume. For procedures utilizing predilution mode: set buffer volume as -1. In the predilution mode, the maximum volume that may be aspirated from the cuvette is 150 µL.
Incubation	Incubation time in seconds before the next pipetting step. (Range = 15 - 600 seconds).
next step	Index position for the next pipetting step (1-4). Last reagent added must always be programmed as S4.

a. Enter the procedure parameters as defined by the reagent manufacturer's application for the AMAX 200.
b. When all parameters have been entered, press **<Esc>** to return to the "Test parameters" dialog window.

19.2.1.4 Data Reduction

The "Data reduction" section controls the result-reporting format.

Move the cursor to the "Data reduction" section and press **<Enter>**. The "Data reduction" sub-window opens.

[Data reduction]

```
Data reduction    Measuring unit    Normal range
   C              %                 50 - 150
   T              Sec
   N
```

Test Parameters - Data reduction	
Parameter	**Setting Definition**
Data reduction	Code for the three data reduction methods: N = Not used T = Time or absorbance (mE) R = Ratio or INR C = Curve calculation
Measuring unit	Measuring unit definition as it will appear on the result list and patient report.
Normal range	Reference range as it will appear on the patient report.

a. Enter the data reduction parameters as defined by the reagent manufacturer's application for the AMAX 200. All entered data reduction types will be included in the patient result list and report. All data reduction information will be printed in the real-time result printout regardless of the data reduction entries. If the reported result is calculated from a calibration curve, "C" must be included in the data reduction section. **If the calculated result is to be displayed in the Quick-Start screen, "C" must be listed as the first reporting option.** If the calibration curve is deleted, "C" must be removed from this section.

b. When all parameters have been entered, press **<Esc>** to return to the "Test parameters" dialog window.

19.2.1.5 Statistics

20.6

The "Statistics" section controls how patient data is sorted for distribution statistics.

Move the cursor to the "Statistics" section and press **<Enter>**.

The "Statistics" sub-window opens.

[Statistics]

		Range	
	Eval.	From	to
Statistics	C	1	200

Test Parameters - Statistics	
Parameter	**Setting Definition**
Statistics - Evaluation field	Enter the code representing how patient distribution statistics are to be sorted and stored: N = Not used. No results will be stored. T = Time or absorbance R = Ratio or INR C = Curve calculation
Statistics - Range from	Minimum value to be used in sorting patient results.
Statistics - Range to	Maximum value to be used in sorting patient results.

a. Enter the Statistics parameters according to how you want them to be stored, sorted and displayed. If the calibration curve is deleted and "C" is a selected type, "C" must be removed from this section. If the data reduction type for a test is changed, all stored data for that test will be deleted.
b. When all parameters have been entered, press **<Esc>** to return to the "Test parameters" dialog window.

19.2.2 Undo Test Parameter Definition

If you decide not to continue with the test parameter definition, press <F10:Undo> when in the "Test parameter" dialog window. The <F10> undo procedure must be performed prior to exiting the "Test parameter" dialog window. Once the window has been exited, the new test will be part of the Test List.

19.2.3 Exiting Test Parameter Definition

When all sections have been completed, close the "Test parameter" dialog window by pressing **<Esc>**. The "Test parameters" dialog window cannot be exited if a procedural error exists. The error will be indicated by a red field. Correct entry error(s). The most common procedural errors are:

- Incorrect dilution protocol
- Unopposed values in calibration curve columns
- Calibration curve deleted but "C" is selected in either "Data reduction" or "Statistics"

As soon as the error condition is corrected, exit from the window is allowed.

19.2.4 Saving Test Parameter Definition

During the exit procedure, you have the option of printing the programmed parameters. Parameters may be **printed** by responding **<y><Enter>** in response to "print? NO". If **no printout** is desired, respond by pressing **<Enter>**. It is recommended that a hard-copy printout be kept of all test parameters. Anytime permanent modifications are made to the parameters, the hard-copy file should be updated.

You have the option of either saving or not saving any modifications to the hard disc (or other designated drive and/or path).

A. **Not to save**: When the test parameters are modified they will be active as soon as any Test Group which includes this test is selected. The parameters just entered are stored only in RAM memory. The "old" parameters are not overwritten. The new parameters are active until such time that the operating program is exited (either voluntarily with <End> or involuntarily with a fatal operating error). The "old" parameters will be in effect on system restart. Respond to **"Save updatings? NO"** with **<Enter>**.
B. **Save**: When the test parameters are saved, the parameters just entered overwrite the stored test parameters. Any modifications made will be active when the system is rebooted. Respond to **"Save updatings? NO"** with **<y><Enter>**.

ATTENTION!
If this test is included in the currently active Test Group, the Test Group must be reselected to initiate any modifications.

19.2.5 Copy Test Parameter Definition from one Test to Another

A complete set of test parameters may be copied to a new position in the Test List. This is particularly useful when setting up a series of tests that have very similar parameters. It may also be used to close gaps left in the Test List when a test is deleted.

ATTENTION!
The copy function is not a "move" procedure. If a test is copied to a new position and then deleted from its old position, all data associated with the test that is stored in the patient archive will be lost. "Move" a test only if the archive file has just been reformatted.

To copy a complete set of parameters to an empty Test List position:

A. Open the “Test list” selection dialog window (<System> <Parameters> <Tests>). Move the cursor to an **empty position** and press **<Enter>**.

B. With the “Test parameters” dialog window open, press **<F7:Copy>**.

```
Copy test ? NO
```

Confirm with **<y><Enter>**. The “Test List” selection window is displayed. Move the cursor to the test whose parameters you want copy and press **<Enter>**.

The parameters from the copied test will be transferred into the new position. Make appropriate modifications as described above.

19.2.6 To Delete a Test from the Test List

A. Before a test may be deleted, the test must be removed from all Test Groups. (<System> <Parameters> <Test groups>) A message disallowing the deletion request will be displayed if the test is a member of any Test Group.

19.1.1.5

B. Open the “Test list” selection dialog window (<System> <Parameters> <Tests>). Move the cursor to the **test to be deleted** and press **<Enter>**.

C. With the “Test parameters” dialog window open, press **<F9:Delete>**.

```
Do you want to delete ? NO
```

Confirm deletion with **<y><Enter>**. Deny deletion with **<Enter>**.

19.2.7 Predilution Mode

In “normal” dilution mode, a volume of undiluted sample is added to a volume of reagent that will result in the desired dilution ratio. At dilutions exceeding 1:20 (e.g., 5 µL Sample + 95 µL reagent), the amount of reagent required for testing becomes excessive. The predilution mode is used to prepare dilutions in excess of 1:20. The highest primary sample dilution that may be prepared is 1:100. The highest calibration dilution that may be prepared is approximately 1:23,250 (1:100 primary + 1:233 secondary).

The predilution is done in a cuvette positioned in the cuvette transfer position. The volumes of plasma and diluent are calculated to a total volume of 700 µL. If necessary, the diluent is dispensed in several steps.

The desired dilution factor is entered in the “dilution r” field of the “Calibration” section.

In a predilution procedure, a buffer of some type is used to prepare the dilution. An entry of **-1** in the buffer volume position activates the predilution mode. **The pipetting mode must be “normal” (0).**

The sample volume entered is the amount of diluted sample that is to be used for testing. **The maximum volume that may be aspirated from the cuvette is 150 µL.** For single sampling, enter any volume between 5 and 150 µL. For duplicate sampling, enter any volume between 5 and 75 µL.

The correct adjustment of the “Levels” for predilution is critical. The cuvette must be at the correct height; the probe must be dispensing at the correct height; and, when aspirating, the probe must go far enough into the cuvette to be able to withdraw the specified volume.

19.5.4

19.2.8 Derived Fibrinogen

Test list position 33 is reserved for Derived Fibrinogen. No other test may be programmed into position 33. Derived Fibrinogen is not a stand-alone test. It is calculated from the turbidity generated during performance of optical prothrombin time.

With certain prerequisites in place, a Derived Fibrinogen result is automatically calculated whenever an optical PT is performed.

A. Optically measured PT must be programmed into Test List position 1;

B. PT Timeout = > 100 seconds;

C. Derived Fibrinogen test definition settings:

   a. Calibration section - Time-out = 90 seconds.
   b. Calibration section - A calibration curve is generated by measuring the optical-PT. Optical-PT must defined in position 1 of the Test List and the above prerequisite conditions must be met. Best correlation will be obtained using fresh patient plasma, with Clauss-established fibrinogen values, as standards. The samples selected as standards should span the reportable range. The Clauss fibrinogen concentration is entered into the value column in the Derived Fibrinogen calibration section. After measuring these plasmas as optical-PT´s in duplicate, enter the averaged mE Values opposite the corresponding concentration in the Sec/mE column of the calibration Section of the Derived Fibrinogen test definition.
   c. Procedure section - Not programmed.
   d. Data reduction section - Program as for any other test.
   e. Statistics section - Program as for any other test.

19.3 Reagent Layout

Password system = Laboratory-defined password.
PIN security system enabled. PIN access level = 2 or 1.

A Reagent Layout defines the exact location of a group of reagents that is used as a unit. Up to 12 Reagent Layouts may be defined. Reagent Layouts are the link between Test Groups and Reagents. Reagents are assigned positions in a Reagent Layout. A Reagent Layout is assigned to every Test Group. Whenever that Test Group is active, the assigned Reagent Layout is active.

Any associated reagents must have been previously defined.

19.4

To open the “Reagent layout” selection window:

<System><Password><Parameters>. Press **<l>** or move the cursor to **“Reagent layout”** and press **<Enter>**.

```
Layout
Routine
Quick Start
PTT/AT3/HEP
PT-M/PTT-O
INFAC
EXFAC
```

1. To define a new Reagent layout, move the cursor to an **empty position** and press **<Enter>**.
2. To modify or delete a previously defined Reagent Layout, move the cursor to the **desired layout** and press **<Enter>**.

   The “Reagent layout” dialog window is displayed.

[Reagent layout]

```
Ord. Number :12     Description: Quick Start

   1.Ring (outer)        2.Ring (middle)        3.Ring (inner)

1 Stat                9 ThromboMAX           17
2 Stat               10                      18 APTT
3 Stat               11                      19 Calcium Chloride
4 Stat               12                      20
5                    13                      21 Thrombin (FIB)
6                    14                      22
7                    15 Imidazole Buffer     23
8                    16                      24
```

   The “Ord. number” is the number associated with the position selected.

19.3.1 To Define or Modify a Reagent Layout

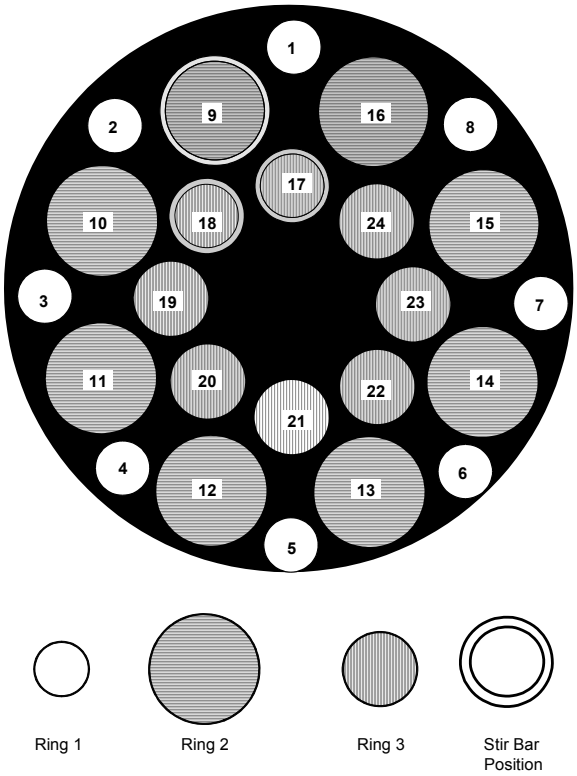
A. Type in a descriptive name that will identify the layout (character limit = 20). This is the name that will appear in the "Reagent layout" selection window.

B. There are 24 positions in a reagent tray. These are arranged in three rings.

   a. The outer ring has eight positions that will hold 12-13 mm containers. The outer ring may be used to position either Stats or small volume reagents.

   b. The middle ring has eight 32 mm positions. Position 9 is a stirred position. There are adapters to convert the large middle ring positions to the smaller inner and outer ring sizes.

   c. The inner ring has eight 25 mm positions. Positions 17 and 18 are stirred positions. There are adapters to convert the inner ring positions to the smaller outer ring size.



Positions should be selected that are appropriate to the volume usage for each reagent. Any particulate reagent must be placed in one of the stirred positions (9, 17 and 18).

Most laboratories have multiple reagent layouts. It is recommended that when a reagent is assigned to more than one layout, the positioning be the same in all layouts. This will avoid inadvertent misplacement of reagents.

To assign a reagent to a position, move the cursor to the position to be assigned. Either enter the Reagent Code Number or press **<F1:Reagent list>** to bring up the "Reagent list". Move the cursor to the appropriate reagent and press **<Enter>**.

Reagent	Expiration
ThromboMAX	01/04/00
Thrombin Time	01/10/00
ALEXIN	01/06/01
Calcium Chloride	01/12/01
Thrombin (FIB)	01/01/00
Imidazole Buffer	01/01/02
F8 Deficient Plasma	01/31/00
F9 Deficient Plasma	06/30/00
AT Heparin/Thrombin	11/30/99
AT Substrate	11/30/99

A reagent may only be assigned to one position per layout. A message disallowing a double assignment will be displayed. To move a reagent from one

position to another position in the layout, remove the reagent from the first assigned position by pressing **<space><Enter>** or **<Delete>**.

Continue as above until all reagents appropriate to the layout are assigned.

a. Stats are sampled from the outer ring (positions 1 - 8) of the reagent tray. If the Reagent Layout is to be used in Stat circumstances, the Stat positions must be assigned. Up to 8 positions may be assigned as Stat positions. Move the cursor to the positions you want to assign for Stats and press **<F2>**. Previously assigned Stat positions may be deleted by following the same procedure. The "Stat" menu will reflect the number of available Stat positions whenever a Test Group which has this layout assigned to it is active.

b. New entries or modifications may be abandoned by pressing **<F10>**. The discard procedure must be done prior to exiting from the "Reagent layout" dialog window.

c. When addition or removal of reagents from the layout is completed, press **<Esc>** to exit the window.

19.3.2 To Delete a Previously Defined Layout

A. A Reagent Layout cannot be deleted if it is assigned to any Test Group. If the layout is assigned to any Test Group, a message disallowing the deletion request will be displayed. To delete a layout that is assigned to a Test Group, change the Reagent Layout assignment for any Test Group assigned to that layout.

19.1.3

B. Open the "Reagent layout" selection window (**<System><Password><Parameters><Reagent layout>**). Move the cursor to the layout you wish to delete and press **<F9:Delete>**.

```
Do you want to delete ? NO
```

Confirm deletion with **<y><Enter>**. Deny deletion with **<Enter>**.

19.4 Reagent

Password system = Laboratory-defined password.
PIN security system = 2 and 1.

Up to 50 reagents may be defined. Reagents are different and need to be handled in different ways to obtain optimal overall performance. The reagent definition provides specific information about each reagent.

Reagents are assigned to tests. A reagent may be assigned to multiple tests. Reagents are assigned positions in Reagent Layouts. A reagent may be assigned to multiple layouts.

19.4.1 To Define a New Reagent or Modify a Previously Defined Reagent

A. **<System><Parameters>**. Open the "Reagent list" by pressing **<r>** or by moving the cursor to **"Reagent"** and pressing **<Enter>**.

[Reagent List]

Reagent	Expiration
ThromboMAX	01/04/00
Thrombin Time	01/10/00
ALEXIN	01/06/01
Calcium Chloride	01/12/01
Thrombin (FIB)	01/01/00
Imidazole Buffer	01/01/02
F8 Deficient Plasma	01/31/00
F9 Deficient Plasma	06/30/00
AT Thrombin/Heparin	11/30/99
AT Substrate	11/30/99

To **define** a new reagent, move the cursor to an empty position and press **<Enter>**.

To **modify** a reagent definition, move the cursor to the appropriate reagent and press **<Enter>**.

The "Reagent definition" dialog window opens.

F9:Delete F10:Undo

[Reagent definition]

```
Ord. Number   :1

Name          :ThromboMAX

Manufact.     :Sigma
Lot No        :049H6204
Expiration    :01/04/00

Disp. speed   :0

Wash cycles   :4
Cleaner       :NO
Intra-Clean   :NO

Min. volume   :2000

Max. volume   :10000
```

Parameters - Reagent Definition	
Parameter	**Setting Definition**
Ord. Number	Position in Reagent List. Automatic instrument entry.
Name	Name of reagent. Character limit = 20
Manufact.	Name of reagent manufacturer. Character limit = 20.
Lot No.	Lot number currently in use. Character limit = 20.
Expiration	Expiration date of lot currently in use. (MM/DD/YY)
Disp. speed	Increases or decreases the individual reagent dispense speed relative to the default speed set in <System><Parameters><Pump>. Entry of a negative number (-n) increases the speed. Entry of a positive number (+n) decreases the speed. (-5 to +5)

Wash cycles	Number of wash cycles after pipetting this reagent. 0.8 ml water is used per programmed wash cycle. (1-10)
Cleaner	Use a cleaner when washing? Yes/No. Volume used is 150% of programmed reagent volume.
Intra-Clean	Use cleaner between each pipetting of this reagent? Yes/No.
Min. volume	Minimum volume in ml that must be present at start of and during processing. Signals reagent refill alert. Limits = 100-10000 µL.
Max. volume	Maximum volume in ml of the reagent container. Controls the bar proportions in Reagent Overview. Limits = 1000-20000 µL.

B. Enter the Reagent Definition parameters as defined by the reagent manufacturer's application for the AMAX 200.

C. New entries or modifications may be abandoned by pressing **<F10:Undo>**. The discard procedure must be done prior to exiting from the "Reagent definition" dialog window.

D. When all parameters have been entered, press **<Esc>** to end and store the parameters. The reagent will now appear on the "Reagent List".

19.4.2 To Delete a Reagent

A. A reagent cannot be deleted if it is assigned to any Reagent Layout or Test Definition. Remove from all layouts and tests. If the reagent is assigned to either layouts or tests, a message disallowing the deletion request will be displayed.

19.2.3
19.3

B. Open the "Reagent list" selection window (<System> <Parameters> <Reagent>). Move the cursor to the reagent you wish to delete and press **<F9:Delete>**.

```
Do you want to delete ? NO
```

Confirm deletion with **<y><Enter>**. Deny deletion with **<Enter>**.

19.5 Levels

Password system = Service password.
PIN security system = 4.

The "Levels" option defines the physical dimensions and z-axis (up and down) coordinates of the reagent containers. The "Levels" definition tells the instrument the probe position to begin aspirating or dispensing; where the container bottom and top are; and, the diameter of the container. In addition to the level sensing and probe positioning functions, this information is used to monitor reagent usage.

"Levels" are set for 6 locations. For accurate usage monitoring, all containers within the location area must be the same size. Monitoring will be unreliable if containers of mixed sizes are used within a location group.

Because these settings are critical to proper performance of the pipetting procedures, access to the "Levels" option is restricted to service level Operators.

With the entry of the service password, the “Levels” selection window is displayed.

```
Wash II
Samples
1. Reagent ring
2. Reagent ring
3. Reagent ring
Predilution
```

Move the cursor to the location group to be defined and press **<Enter>**.

The “Levels” dialog window will open. The predilution dialog window is slightly different.

[F1: Read level]

```
1. Reagent ring
Max. Level     :2336
Bottom         :2561
Diameter       :10
```

[F1: Read level]

```
Predilution
Max. Level         :411
Bottom             :692
Cuvette height     :42
```

Parameters - Levels Definition	
Parameter	**Setting Definition**
Max. Level	Wash II, and Reagent rings 1, 2, 3: Z-axis position of the maximum level of reagent or sample that will be in the container. Provides the height of reagent in the container used in the reagent usage-monitoring algorithm. Sample: Z-axis position (down-stop position) of the probe when preparing dilutions. Diluent-dispensing position. Predilution: Z-axis position (down-stop position) of the probe when dispensing into the predilution cuvette. Diluent-dispensing position.
Bottom	Sample, Wash II, and Reagent rings 1, 2, 3: Z-axis position of the bottom of the container. This setting determines how far down the probe will go. For reagent usage monitoring, provides the depth of reagent in the container. Predilution: Z-axis position (down-stop position) of the probe when aspirating out of the predilution cuvette. Probe dilution-aspiration height.
Diameter	Sample, Wash II, and Reagent rings 1, 2, 3: Internal diameter of the container in mm. For reagent usage monitoring,2 provides the width of reagent in the container. Predilution: Not applicable.
Cuvette height	Sample, Wash II, and Reagent rings 1, 2, 3: Not applicable. Predilution: Height of the cuvette in the incubation rail.

The most efficient sequence in setting levels is backwards (Diameter ➔ Bottom ➔ Max. Level).

19.5.1 Diameter

Sample, Reagent Rings 1, 2 and 3: Move the cursor to the “Diameter” field. Measure the internal diameter in millimeters (mm) of the container that will be used in the location. Type the measured diameter into the diameter field. Provides the width value used in the reagent usage calculation. The diameter setting also determines the depth that the probe goes into the container.

Wash II: Move the cursor to the “Diameter” field. To assure that the probe always goes into the cleaner than deeper than into any reagent, an empirical setting of 15 is used.

19.5.2 Bottom Levels

A. **Sample – Transfer tube:** Follow the reagent rings procedure. Note that because of calibration circumstances, this is the usual setting used for the sample bottom level. Assure that the volume of plasma in primary tubes is at least 10 mm above the red cell/plasma interface.

Sample – Primary tube: If all sampling is from primary tubes and calibration can be performed using special spring-loaded adapters, a setting of the bottom level to represent the interface level assures that the probe will not go below the red cell/plasma interface. Move the cursor to the "Bottom" field. Place a representative sample container in a position in the sample tray that the probe can access. Pipette a sufficient amount of dH_2O into the tube to be above the typical interface (approximately 60% of the total sample volume). Carefully move the robot arm to the position and move the probe down to where it just touches the water in the tube. Press **<F1>** to read the position.

B. **Wash II**: Move the cursor to the "Bottom" field. Decontaminant may be used either in a 15 ml container or poured into the trough. If a bottle container is to be used, position an **empty bottle** at the far right side of the trough. Carefully move the robot arm to the position and move the probe down to where it just touches the bottom of the container or trough. Back up a few millimeters. Press **<F1>** to read the position. To avoid damage to the probe and to avoid false level sensing, it is important that the position not be on the actual bottom. The aspiration position of the probe is approximately 2 mm deeper than the point at which it senses liquid. If the probe repeatedly hits the bottom of the container, damage to the probe will be incurred and consequently dispense speed will be affected. Any residual liquid covering the bottom of the container will cause false level sensing and no warning of an insufficient level of decontaminant will be given.

C. **Reagent Rings 1, 2 and 3**: Move the cursor to the "Bottom" field. Add a sufficient amount of dH_2O to provide a depth of approximately 2-mm in a reagent container. Place the container in a reagent tray position that the probe can access. Carefully move the robot arm to the position and move the probe down to where it just touches the liquid. An alternative is to use an empty bottle, move the probe down to where it just touches the bottom of the tube and then back up a few millimeters. Press **<F1>** to read the position. To avoid damage to the probe and to avoid false level sensing, it is important that the position not be on the actual bottom. The aspiration position of the probe is approximately 2 mm deeper than the point at which it senses liquid. If the probe repeatedly hits the bottom of the container, damage to the probe will be incurred and consequently dispense speed will be affected. Any residual liquid covering the bottom of the container will cause false level sensing and no warning of an insufficient level of reagent will be given.

WARNING!
To avoid contamination of the outside of the probe it is important that neither reagent or sample is in the container when setting the bottom level.

19.5.3 Maximum Level

Sample: The maximum level setting determines the height from which diluent is dispensed when preparing calibration dilutions. To assure that all sample and diluent are delivered to the bottom of the tube and to avoid foaming, the level is set to approximately ¾ to 1" above the bottom of the tube. Move the cursor to the "Max. Level" field. Place an empty sample tube in a sample-tray position that the probe can access. Carefully move the robot arm to the position and move the probe down to where it just touches the bottom of the tube. Back up approximately ¾ to 1". Press **<F1>** to read the position.

Wash II: To avoid a premature cleaner-low warning, the Wash II maximum level is set to an empirical ¾ to 1" above the bottom of the container. Move the cursor to the "Max. Level" field. Place an empty contaminant container into the wash trough area. Carefully move the robot arm to the position and move the probe down to where it just touches the bottom of the container. Back up approximately ¾ to 1". Press **<F1>** to read the position.

Reagent Rings 1, 2 and 3: The maximum level setting provides the height of reagent in the container used in the reagent usage-monitoring algorithm. It represents the maximum volume of reagent that is expected to be in the container. Move the cursor to the "Max. Level" field. Place the appropriate container in a reagent-tray position that the probe can access. Pipette into the container the amount of reagent that will be used in this container size. Carefully move the robot arm to the position and move the probe down to where it just touches the top of the water. Press **<F1>** to read the position.

19.5.4 Predilution Levels

Correct level adjustments are critical to the performance of the Predilution Mode.

As soon as Predilution is selected, a cuvette will be transferred into the predilution position in the incubation rail. **The cuvette height must be adjusted prior to setting the maximum and bottom levels.**

A. **Cuvette height adjustment**: There is a brass pin that presses against the back right side of the cuvette and holds it in place during the predilution procedure. The pin is retracted during the transfer process. After the cuvette has been transferred, the pin is released. The cuvette height is adjusted to a position where the pin engages the side of the cuvette. This usually corresponds to a height that brings the top of the cuvette almost level with the top of the incubation rail. The cuvette height should not be adjusted to where the cuvette is above or resting on the pin.

   Prior to entry into the Predilution window, place an empty cuvette into the cuvette transfer position. The pin will be in its fully engaged position and the cuvette will be resting on top of the pin. The final cuvette height position should be approximately 4-6 mm below this position. Remove the cuvette. Note: If already in this window with a cuvette transferred into the incubation rail, press **<Esc>**. The cuvette will be automatically discarded.

   Select Predilution from the Levels selection window. A cuvette will be transferred into the predilution position. Check the height of the cuvette in comparison to the height of the cuvette when resting on the pin. Adjust height up (higher value) or down (lower value) accordingly. Type in an appropriate value. The window must be exited to check the new position. Press **<Esc>** to exit. The cuvette in the rail will be discarded. Re-enter the Predilution window and check

the new cuvette height positioning. Repeat the exit-enter procedure until cuvette is at the desired height.

B. **Maximum level, Predilution**: The maximum level setting determines the height from which the probe will dispense sample/buffer mixture into the predilution cuvette. After the cuvette height has been adjusted to its final position, carefully move the robot arm to the position and move the probe down to a position where the tip is approximately 2-3 mm inside the top of the cuvette rim. Press **<F1>** to read the position.

C. **Bottom level, Predilution**: The maximum level setting determines the depth from which the probe will aspirate sample/buffer mixture from the predilution cuvette. This setting is critical and assures that the probe will be able to aspirate the programmed volume (maximum total volume = 150 µL) from the predilution cuvette. Move the probe down into the cuvette to a position where the probe body just barely touches the top of the cuvette. Press **<F1>** to read the position.

When all levels for a location have been set, exit the dialog window by pressing **<Esc>**.

19.6 Pump

Password system = Service password.
PIN security system = 4.

The “Pump” parameters control the aspiration/dispense characteristics of the syringe.

Because these settings are critical to proper performance of the pipetting procedures, access to the “Pump” option is restricted to service level Operators.

With the entry of the service password, the “Pump parameters” dialog window is displayed.

[Pump parameters]

```
Speed wash          :1

Speed sample        :14
Speed dispense      :3

Acceleration        :6
Cut-Off             :8

Step / µL           :6

Air-gap             :5
Back-lash corr.     :20

Wash cycles         :10

Stirrer speed       :2
```

Parameters - Pump Definition	
Parameter	**Setting Definition**
Speed wash	Speed of wash cycle. 0 = fastest; 40 = slowest.
Speed sample	Speed of sample and reagent aspiration. 0 = fastest; 40 = slowest.
Speed dispense	Speed of sample and reagent dispense. 0 = fastest; 40 = slowest.
Acceleration	Acceleration of syringe plunger movement. (Limits = 1-20)
Cut-Off	Final speed of brake threshold. (Limits = 0 - 20)

Steps/ml	Number of motor steps per microliter. (Limits = 1 - 20)
Air-gap	Volume in ml of air bubble separating aspirated liquids in probe. (Limits = 1 - 40)
Back-lash corr.	Number of steps to attain mechanical balance. (Limits = 1 - 50)
Wash cycles	Number of wash cycles that will be done after "System fluid low" error message. (Limits = 0 - 500)
Stirrer speed	Rotation speed of magnetic stirrer. (Limits = 1 - 10)

When all parameters have been entered, press **<Esc>** to end and store the parameters.

19.7 Measuring Mode

Password system = Laboratory-defined password.
PIN security system = 2 and 1.

There are over 40 possible ways that an optical reaction may be measured. Nine (9) of these modes may be active at any given time. The "Measuring mode" option is used to select which 9 will be available for use. These 9 selected modes are the "Measuring Mode" options that are displayed when programming the test parameters "Procedure" section.

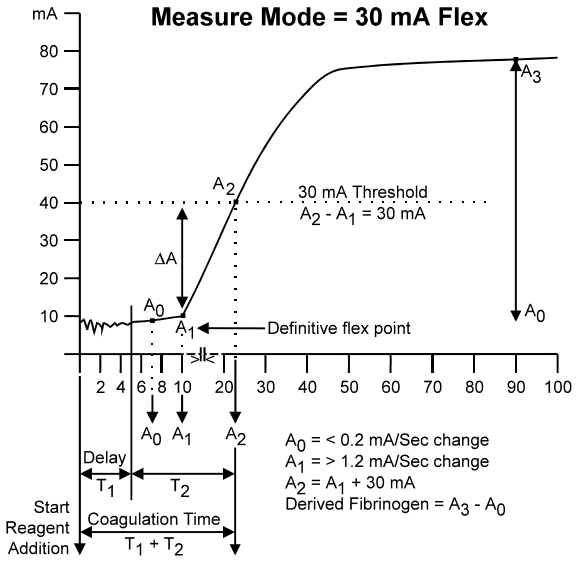
19.2.3

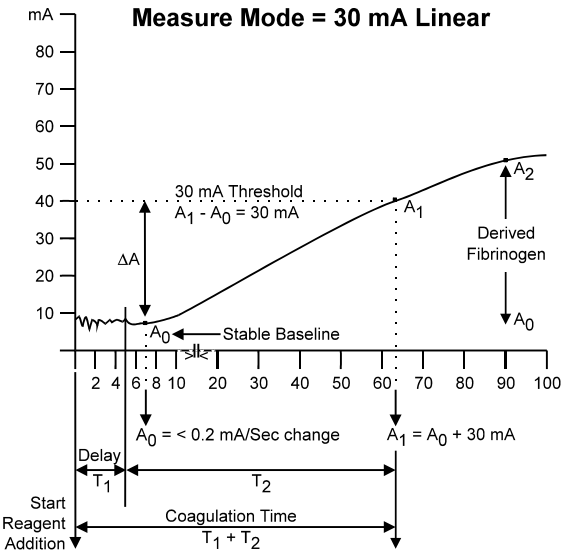
<System><Parameters>. Open the "Measuring mode" dialog window by pressing **<m>** or by moving the cursor to **"Meas. mode"** and pressing **<Enter>**.

[Meas. Mode]

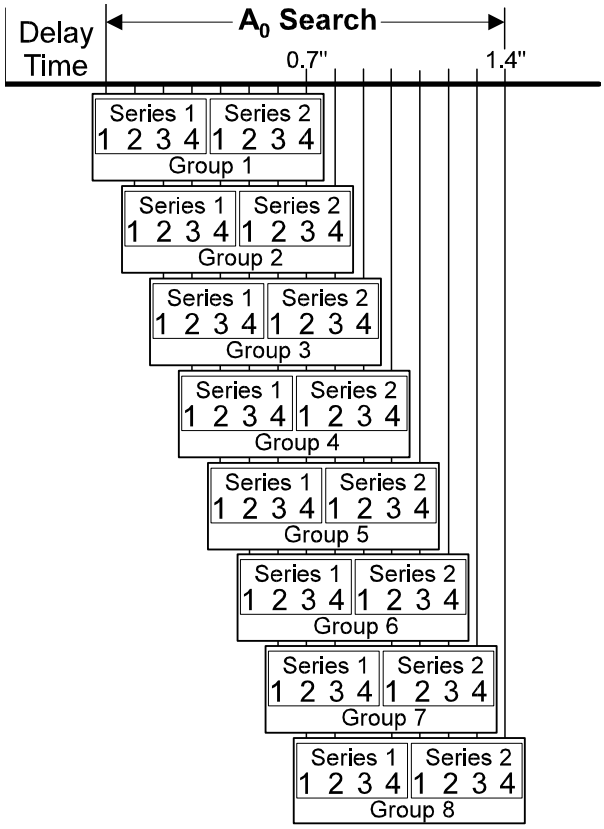
	Clott. Linear		Clott. Flex.Pt.		Chromogen
I	10 milli E		10 milli E		30, 60, 90
	20 milli E		20 milli E	D	10, 20, 30
A	30 milli E	B	30 milli E	E	15, 30, 45
	40 milli E		40 milli E		20, 30, 40
	50 milli E		50 milli E		20, 40, 60
	60 milli E		60 milli E		10, 40, 70
	70 milli E		70 milli E		60,120,180
	5 milli E		5 milli E		10,190,370
C	15 milli E	F	15 milli E		10,265,520
	25 milli E		25 milli E		60, 90,120
	35 milli E		35 milli E		180,210,240
	45 milli E		45 milli E		210,240,270
	55 milli E		55 milli E		10,155,300
	10 mE max	G	15 mE max		30, 60, 90
H	Delta E				

There are two basic types of optical measuring modes used in tests that have fibrin formation as the endpoint. The difference between the two types is when the time measurement for ΔE begins. Some reactions typically have a point where there is a definitive absorbance increase when coagulation begins (flex point). For other reactions, the beginning of coagulation is not as definitive (linear).





The search for A_0:



OD measurements are taken at 0.1 second intervals starting at the end of the delay time.

Two series of 4 OD measurements are taken at 0.1 second intervals.

The average OD of each series is calculated.

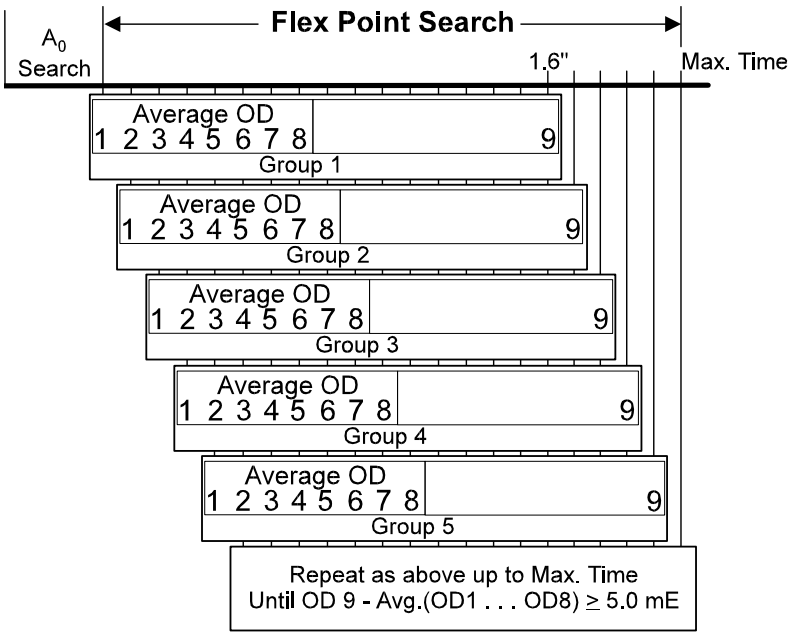
If (Avg. OD_{S2}) – (Avg. OD_{S1}) $\leq$ 1.3 mE, the search for A_0 is successful.

If (Avg. OD_{S2}) – (Avg. OD_{S1}) > 1.3 mE, the next group of OD readings is evaluated.

In Linear mode, this process may be repeated up to a maximum of 8 times. If after 8 iterations a stable baseline has not been found, the value at the end of the 8th iteration is taken as A_0.

In Flex mode, this process may be repeated up to a maximum time of 20 seconds. If at this time a stable baseline is not found, the result will be No Coagulation (NC).

The search for the Flex Point:



In a manner similar to that for the search for A0, a series of 9 OD measurements are taken over a 1.6 second interval.

The average of the first 8 readings is calculated.

If $(OD_{9)} - Avg.(OD_1 \ldots OD_8) \geq 5$ mE, the search for the flex point is successful.

If $(OD_{9)} - Avg.(OD_1 \ldots OD_8) < 5$ mE, the search for the flex point is unsuccessful and the next group is evaluated. The search will continue up to the defined Max. Time. If at Max Time the flex point has not been found, the result will be No Coagulation (NC).

In the linear measuring mode, the delay phase ends, a stable baseline is found (A_0) and Δ measurement begins either as soon as A_0 is found or after 8 attempts to find a stable baseline. The shortest valid time that can be measured in linear mode is the delay time plus 0.8 seconds (the first reading after A_0 is found). In the flex point-measuring mode, the delay phase ends, a stable baseline is found (A_0) and Δ measurement begins when there is a definitive absorbance increase (A_1). The instrument starts looking for the flex point after a stable baseline is found. The shortest valid time that can be measured in flex mode is the delay time plus 0.7 (the search for A_0 time) seconds plus 1.7 seconds (the first reading after the flex point is found).

The selection of the basic type of measuring mode is based on the specific test reaction. Different formulations of reagent for the same test may vary in their reaction characteristics. The reaction characteristics of abnormal samples may be very different from normal samples. The measuring mode selected must encompass reaction characteristics representative of both normal and abnormal sample responses.

There are a variety of ΔE choices within each basic measuring mode type.

This choice determines the endpoint (A_1 or A_2). As with basic type determination, different formulations of reagent for the same test may vary in their reaction characteristics and the reaction characteristics of abnormal samples may be very different from normal samples. Abnormal samples are often more indicative of what the ΔE choice should be than are normal samples.

Use the “Graphic” mode (<Measure><Graphic>) to assist in the selection of an appropriate measuring mode.

To select a measuring mode to be included as one of the 9 active optical modes, move the cursor to the desired mode. Type a l**etter (A to I)** that is not assigned to any other test. Confirm with **<Enter>**.

ATTENTION!
Change of assignment will affect all tests using the chosen letter designation. It is recommended that a record be kept of all letters assigned to defined tests and what measuring mode they represent. Inadvertent change of measuring mode may cause erroneous results.

Press **<Esc>** to exit the window.

19.8 Temperature

Password system = Service password.
PIN security system = 4.

Temperature is an important factor in determining the progression rate of coagulation reactions. As such, it must be constantly monitored and controlled within tight guidelines.

The “Temperature” settings determine the range of allowable deviation for each critical temperature area.

Because these settings are critical to overall performance, the “Temperature” option is restricted to service level Operators.

With the entry of the service password, the “Temperature range” dialog window is displayed.

[Temperatur range]

	Warning		Error	
Temperature	<	>	<	>
Sample/Reag.	12	18	10	20
Probe/Incub.	36	40	35	42
Opt.Meas.pos.	36.5	37.5	36	38
Mech.Meas.pos.	36.5	37.5	36	38

Parameters - Temperature Limits	
Parameter	**Setting Definition**
Warning <	Lower limit (°C) to trigger temperature alert
Warning >	Upper limit (°C) to trigger temperature alert
Error <	Lower limit (°C) to trigger emergency abort
Error >	Upper limit (°C) to trigger emergency abort

Use the cursor keys to move within the window. Type in each limit. Note that, because the temperature is so critical in some of these areas, there are programming over-rides for some of these areas. The operating system over-ride will take priority if these limits are set inappropriately.

When all limits have been programmed, press **<Esc>** to exit the window.

19.9 Back up

Password system = Laboratory-defined password.
PIN security system = 2 and 1.

The “Back up” option is used to make a back up copy of all critical testing and system set-up files such as:

- Test groups definition
- Test parameters definition
- Reagent layouts definition
- Reagent definitions
- Panel definitions
- Measuring mode selection definition
- Password
- Pump parameter definitions
- Lock channels settings
- Temperature limit definitions
- XYZ-alignment settings
- Control Definitions

It is recommended that a back up copy of established parameters be prepared on a floppy disc and kept in a safe place. The back up file is made **from** the currently active drive and path **to** the selected drive (hard drive or floppy drive whichever is appropriate).

Patient archive information and associated data is not copied.

During the back up procedure:
[Files in currently active drive/path] ➔ [Selected disc drive]

To prepare a back up file:

1. **<System><Parameters>**. Press **<b>** or move the cursor to **“Back up”** and press **<Enter>**.

   ```
   Hard disc
   Floppy disc
   ```

2. Move the cursor to the location where the back up files are to be copied. If the currently active drive is C and copying will be to the floppy drive (A), insert a 1.44MB/HD disc into drive A. Press **<Enter>** to begin the back up procedure.

At the conclusion of the copy procedure, the back up files will be located on the designated drive.

19.10 Restore

Password system = Laboratory-defined password.
PIN security system = 2 and 1.

The “Restore” option is used to reestablish back up files to the currently selected drive/path. The back up procedure must have been done previously. Back up files are divided into two types:

1. Parameters (testing protocols)(not instrument specific)
   - Test groups definition
   - Test parameters definition
   - Reagent layouts definition
   - Reagent definitions
   - Panel definitions

- Measuring mode selection definition
- Control definitions

2. System set-up (instrument specific files)
   - Password
   - Pump parameter definitions
   - Lock channels settings
   - Temperature limit definitions
   - XYZ-alignment settings

The restore procedure copies the selected type of back up files **from** the selected drive (hard drive or floppy drive) **to** the currently active drive and path.

WARNING!
All affected files in the currently active drive/path will be overwritten during the restore procedure.

During the restore procedure:

[back up system files stored on selected disc drive] ➔ [Currently active drive/path]

Inadvertent and irretrievable loss of important files may be avoided by the initial preparation of a second back up file in the opposite location from which the restore procedure is to done. For example: Back up files have been previously made to a floppy disc. These are the files that you want to re-establish in the currently active drive/path. The currently active drive/path is on the hard disc (c:\). Restoration will be from the floppy drive to the hard disc. Prior to performing the restore procedure from the floppy drive, back up the currently active files to the hard disc. (<Back up><Hard disc>). After performing this back up procedure, there are two sets of back up files. (1) Those previously made to the floppy disc; and, (2) those just prepared on the hard disc. Carryout the restore procedure (<Restore><Floppy disc><Parameters> or <System set-up> as appropriate). At the end of the restore procedure, the files from the floppy disc will have been copied into the currently active drive/path. The previously active files are present in a back up file on the hard disc and may be restored if desired (<Restore><Hard disc><Parameters> or <System set-up> as appropriate). By performing the double back up, nothing is irretrievably lost as long as the second set of back up files is made in the opposite location of the first set of back up files.

19.10.1 To Restore a Back up File

A. **<System><Parameters>**. Press **<s>** or move the cursor to **"Restore"** and press **<Enter>**.

```
Hard disc
Floppy disc
```

Move the cursor to the location where the back up files are located. Press **<Enter>**.

```
Parameters
System set-up
```

Move the cursor to the type of files to be restored. Selecting <Parameters> will result in the copying of all test definition and control definition parameters from the back up files to the current drive/path. Selecting <System set-up> will result in the transfer of all instrument operating parameters.

WARNING!
"Parameter" files may be transferred from one instrument to another. Transfer of "System set-up" files from one instrument to another is not recommended. All alignment, pump and levels parameter definitions from instrument #1 are transferred to instrument #2. These settings are instrument specific and may not be appropriate settings for instrument #2. All such settings will have to be re-established on instrument #2. Access to all of these areas is restricted to authorized service personnel.

B. With the cursor over the selected file type, press **<Enter>** to begin the restoration procedure. At the conclusion of the restore procedure, the back up files will be located in the currently active drive/path and will be the active parameters on system restart or with the “Format data file” procedure.

19.10.2 To Activate the Back up Parameters

A. If the patient archive file contains important patient information that you want to keep, exit from the operating program (<End><Yes>). At the current drive/path prompt, type <a><Enter> to restart the operating program.

B. If there is no patient information that you want to keep, perform the “Format data files” procedure (**<System><Format data files>**).

20 QUALITY CONTROL MENU 20-1
20.1 QC SETUP 20-4
20.1.1 Westgard Definitions 20-4
20.1.1.1 Rule 20-5
20.1.1.2 Enabled 20-5
20.1.1.3 Alarm 20-7
20.1.1.4 Option 20-7
20.1.1.5 Flowchart of Information Transfer 20-9
20.1.2 Controls 20-10
20.1.2.1 Addition of a New Control 20-10
20.1.2.2 To Modify a Previously Defined Control 20-13
20.1.2.3 To Delete a Control 20-15
20.1.2.4 Flowchart of Information Transfer 20-16
20.2 QC FILES 20-17
20.2.1 Create 20-17
20.2.1.1 On an Inactive Test 20-18
20.2.1.2 On an Active Test 20-19
20.2.1.3 On an Undefined or Partially Defined Test 20-19
20.2.1.4 Reactivation of Previously Closed Files 20-19
20.2.2 List 20-21
20.2.3 Export 20-22
20.2.4 Backup 20-22
20.2.5 Restore 20-23
20.2.6 Delete 20-24
20.2.7 Flowchart of Information Transfer. 20-25
20.3 QC CHARTS 20-26
20.3.1 Thumbnail Charts 20-27
20.3.2 Zoom Chart 20-29
20.3.2.1 Introduction 20-29
20.3.2.2 Commands, Working with the Zoom Chat 20-30
20.3.2.3 Mean30/Mean 20-33
20.3.2.4 Comment on a Data Point 20-33
20.3.2.5 Omit a Data Point. 20-34
20.3.2.6 Append a File 20-35
20.3.2.7 Change the Target Value 20-36
20.3.2.8 New File 20-36
20.3.3 Z-Score Distribution Chart 20-37
20.3.4 Print QC Report 20-37
20.4 RULE SENSITIVITY SETTINGS 20-39
20.5 VIOLATION EXAMPLES 20-41
20.6 DISTRIBUTION 20-45
20.6.1 Distribution Chart and Report 20-45
20.7 CALIBRATION CURVES 20-46
20.8 REFERENCES 20-47

Quality Control Menu

Quality control is a part of the Quality Assurance program of every laboratory. It is the responsibility of each laboratory to define the circumstances for acceptance or rejection of the test results obtained during any analytical run. A well-designed quality control program monitors the many variables that may cause inaccurate patient results and well-chosen decision criteria increase the probability that each result reported is valid.

Although frozen-pooled patient specimens may be used, most laboratories rely on commercial quality control materials. Commercial controls also allow the laboratory the opportunity to participate in external quality control programs that give the participant laboratories pertinent inter- and intra-laboratory comparison information.

Statistical analysis of the data is virtually always the first step. The mean identifies the "target value" and is the basis for data comparison or for calculation of other pertinent statistics. Any change in accuracy will be reflected by a change in the mean. The mean is related to accuracy or systematic error. The standard deviation (SD or s) is the measure of the inherent imprecision in the test procedure. Any change in precision will be reflected by a change in the SD. SD is related to precision or random error. The coefficient of variation (CV) is a measure of the variability related to a specific concentration and reflects method performance over the reportable range.

There is no one "right" way to evaluate quality control results. One commonly used way to decide if QC data is "in-control" or "out-of-control" is to use ± 2 SD as a limit. The data is compared to calculated ± 2 SD limits to determine whether the run is accepted or rejected. Data is plotted on Levey-Jennings charts that provide a visual record of the QC results. Laboratories using only ± 2 SD as a decision criterion will often reject valid runs. Failure to allow for valid points lying between 2 and 3 SD will result in rejecting 5% of all acceptable runs when using one control, 9% when using two controls, 14% when using three controls and 18% when using four controls.[1, 2, 3] The net result in having to unnecessarily repeat runs is loss of time and money. Both are commodities that no laboratory can afford to ignore.[1, 2, 3]

Use of ± 3 SD as the decision criteria greatly reduces the problem of false rejections but also reduces error detection to the point that medically important errors may go undetected.

Another approach is to use "multirule" procedures. Multirule-QC uses more than one decision criteria to determine whether a run is in-control or out-of-control. The Westgard multirule procedure uses five different control rules in conjunction with the ± 2 SD criterion to judge the acceptability of a run. The purpose of using multirules is to increase the probability of error detection and to decrease the number of false rejections. By combining rules that individually have a low probability of false rejection, error detection is increased and false alarms are minimized. In addition, the rule or rules violated may give some indication of the type of error that has occurred. Some rules are better indicators of systematic error, others of random error.[1, 2, 3]

The probability for error detection always goes up when the number of measurements used for the assessment is increased. The real benefit of using the Westgard multirules or any other multirule combination is increasing the number of measurements used in the assessment but not increasing the number of controls assayed. Assessing results across materials as well as within material increases the number of measurements. Assessing results across-runs as well as within-run increases the number of measurements. The odds of being able to detect errors increases and problems with a procedure may be identified sooner.[1]

Westgard Multirules		
Rule	**Definition**	**Error Type**
1-2s	Warning rule. One control result exceeds the mean > ± 2 SD. In manual applications, a result > ± 2 SD triggers the inspection of data by the other rules. In computer assisted programs, 1-2s is not needed since the program can automatically apply all the chosen rules.	Random or systematic
1-3s	One control result exceeds the mean > ± 3 SD. This is the "action" limit on Levey-Jennings charts. A violation of 1-3s indicates an increase in the test imprecision.	Random or large systematic
2-2s	Two consecutive control results exceed the mean > ± 2 SD in the same direction (either mean + 2 SD or mean – 2 SD). May be within-material or across-materials; within-run or across-runs. Within-material violations point to systematic errors occurring at one concentration. Across-material violations point to systematic error occurring throughout the range.	Systematic
R-4s	Range rule. In manual applications, R-4s is usually a qualitative assessment and is invoked whenever one control in the run exceeds the + 2 SD limit and the other exceeds the – 2 SD limit. In computer assisted programs, the rule is used quantitatively by measuring the exact range between two consecutive controls. R-4s is invoked when the difference between the two results exceeds 4 SD. A violation of R-4s indicates an increase in the test imprecision. To maintain the R-4s as a random error indicator, it should only be used within-run. It should be used across-materials unless multiples of the same control are within the run.	Random
4-1s	Four consecutive control results exceeding the mean > ± 1 SD in the same direction. May be consecutive measurements within-material; or, may be across-materials. Usually the assessment is across-runs unless at least four controls are within the run. A violation of 4-1s indicates a change in accuracy. As with the 2-2s rule, within-material 4-1s violations point to systematic errors occurring at one concentration. Across-material violations point to systematic error occurring throughout the range.	Systematic
10-m	Shift rule. Ten consecutive control results exceed the mean in the same direction. May be within-material or across-materials. Virtually always occur across-runs unless at least ten controls are within the run. A violation of 10-m indicates a change in accuracy. As with the 2-2s rule and 4-1s, within-material 10-m violations point to systematic errors occurring at one concentration. Across-material violations point to systematic error occurring throughout the range.	Systematic

The Westgard Multirules are a specific grouping of rules: 1-3s, 2-2s, R-4s, 4-1s, and 10-m and are usually applied when using either 2 or 4 control materials. Several common modifications or alternatives are used as appropriate to the control system in use. For example, when three control materials are in use, rules that work in multiples of three make more mathematical sense.[1, 3] Only those rules that are used in the AMAX 200 QC program are discussed below.

Other Common Multirules		
Rule	**Definition**	**Error Type**
2 of 3-2s	A modification of the 2-2s rule that works better in a 3 control system. Two of the last three control results exceeding the mean > ± 2 SD in the same direction. May be within material or across-materials; within-run or across-runs. In a three control system, the 2 of 3-2s rule is substituted for the 2-2s rule. As with the 2-2s rule, within-material 2 of 3-2s violations point to systematic errors occurring at one concentration. Across-material violations point to systematic error occurring throughout the range.	Systematic
7-t	Trend rule. Seven consecutive control results that are progressively increasing or decreasing. May be within-material or across-materials. Virtually always across-runs unless at least seven controls are within the run. As with the 2-2s rule, within-material 7-t violations point to systematic errors occurring at one concentration. Across-material violations point to systematic error occurring throughout the range.	Systematic

The QC Menu contains options for defining the way that QC data is evaluated and the tools for maintaining established QC files. The operator interacts with multiple dialog windows to optimize the evaluation process to the requirements of the laboratory.

Prior to defining any of the QC options, the following system prerequisites must be in place:

19.4
19.2

- Reagents have been defined; and
- Tests have been defined.

Prior to performing QC testing, the following system prerequisites must be in place:

20.1.2
20.2.1
19.3
19.1

- Controls have been defined;
- QC Files have been created;
- Reagents have been assigned to a Reagent Layout
- Tests have been placed into a Test Group.

To open the "Q.C." menu, press **<q>** or move the cursor to **"Q.C."** and press **<Enter>**.

[Q.C.]

Q.C.Charts	Section 20.3
Q.C.Files	Section 20.2
Q.C. Setup	Section 20.1
Distribution	Section 20.6
Calib. Curve	Section 20.7

Preparing the QC program for use is similar to defining test parameters. It must be done in a specific sequence. The QC Chart is at the top of the QC pyramid. Each QC Chart is associated with both a control material and a test. The control material to use

with each test must be defined. The QC File establishes the relationship between a test and the associated control material. Before the performance may be assessed, the values associated with stable performance must be defined. Before the results may be evaluated, the evaluation criteria must be defined. The Control Definition contains all the assigned values and evaluation criteria for every test associated with it. The Control Definition is the base of the pyramid.

20.1 QC Setup

Password security system = unrestricted
PIN level accesses = 1 (full), 2 (full) and 0 (prohibited)

Before QC test results may be evaluated, limits of acceptability must be defined and the rules used to evaluate the results when these limits are exceeded must be defined. This must be done for every control material being used and for every test being performed on that material. QC Setup is the beginning of this process.

Prior to defining any of the QC options, the following prerequisites must be in place:

- Reagents have been defined; and
- Tests have been defined.

19.4
19.2

To open the "Q.C. Setup" menu, press **<s>** or move the cursor to "**Q.C. Setup**" and press **<Enter>**. The Q.C. Setup submenus are displayed.

```
[QC Setup]
Controls
Westgard Def.
```

Section 20.1.2
Section 20.1.1

20.1.1 Westgard Definitions

Password security system = full access
PIN level accesses = 2 (full), 1 (full) and 0 (prohibited).

Many laboratories have basic QC evaluation guidelines that are used on all, or the majority of, tests. The "Westgard Def" menu is used to define the "default" evaluation rules. Every test on a newly defined control will assume the default rule. If the majority of tests are evaluated using the same rules, setting the default rules will save time when defining the evaluation criteria for each test. Only the exceptions to the rules will require changing rather than having to set all rules for every test.

To open the "Westgard rule setup" dialog window, press **<w>** or move the cursor to "**Westgard Def.**" and press **<Enter>**.

[Westgard rule setup]

Rule	Enabled	Alarm	Option	Opt. Value
1-2s	None	NO	None	0
1-3s	None	NO	None	0
2-2s	None	NO	None	n.a.
R-4s	None	NO	None	n.a.
2-3s	None	NO	None	n.a.
4-1s	None	NO	None	n.a.
10-m	None	NO	None	n.a.
7-t	None	NO	None	n.a.

20.1.1.1 The **"Rule"** column is the name that will be used when violations occur regardless of how the rule is setup to be used. The rule name is not editable. With one exception, the AMAX 200*AMAX* follows the traditional Westgard nomenclature where SD is denoted as "s" with the number of SDs placed before the "s" and the number of consecutive observations is placed before the number of SDs. A hyphen is used to separate the number of consecutive observations from the number of SDs.

The exception is the "2-3s" rule. Because of field size limitations, the traditional "2 of 3-2s" rule is designated as "2-3s".

20.1.1.2 The "**Enabled**" column is used to turn the corresponding rule on or off. It is also used to determine whether the data is assessed within-material, across-materials or within-control.

The "Westgard Rules" are decision criteria that are used to evaluate control data and to assist in the judgment of control status. A run is rejected when the control results for a specific test meets the rule definition. The rules may be applied in the following ways:

- Within-material/within-run to evaluate the results of a single control material collected within a single run.
- Within-material/across-runs to evaluate the results of a single control material collected from more than one run.
- Across-material/within-run to evaluate the results of two or more control materials collected from within a single run.
- Across-material/across-runs to evaluate the results of two or more control materials collected from two or more runs.

The AMAX 200 is capable of performing the evaluation in all of these ways. In addition, a non-traditional expansion of the rules allows evaluation of different test results on a single control material. This type of evaluation may provide information on the overall performance of a control material. Note that rules enabled in the "Westgard rule setup" screen are used as default assignments. Rule selection for each test on each control may be individually enabled or disabled in the "Control definition" and "QC File Directory" screens.

20.1.2
20.2.2

The type of data assessment is designated by four codes: none, VS, VT and VC. The spacebar serves as a toggle between the codes.

AMAX 200 WESTGARD RULE SETUP: ENABLED SELECTION	
Enable Code	**Type of Data Assessment**
None	Not used for rule evaluation.
VS	Violation within series. A series is data collected from one test on one control material. Within material. Same control, same test. Applied within-run and across-runs. VS evaluation checks for bias or imprecision at one concentration. Points are entered into the VS evaluation counter in the order in which each sample in the series is completed. The evaluation counter is reset to zero when a value is omitted.
VT	Violation within test. Data is collected from one test on two or more control materials. Across-materials. Different controls, same test. Applied within-run and across-runs. VT evaluation checks for bias or imprecision across the measurement range. All control materials with the same test activated will contribute data points into the VT counter. Points are entered into the VT evaluation counter in the order in which each test is completed. The evaluation counter is reset to zero when a value is omitted.
VC	Violation within control. Data is collected from one control material on two or more different tests. Same control, different tests. Applied within-run and across-runs. All tests activated on a particular control will contribute data points into the VC evaluation counter. Points are entered into the VC evaluation counter in the order in which each test on the control is completed. The number of tests activated on the control determines the odds for rule violation. The evaluation counter is reset to zero when a value is omitted.
VS / VT	Combination VS/VT assessment. Checks for violation within-series and within-test. Same control on same test and then different control(s) on same test. Applied within-run and across-runs.
VS / VC	Combination VS/VC assessment. Checks for violation within-series and within-control. Same control on same test and then different tests on same control. Applied within-run and across-runs.
VT / VC	Combination VT/VC assessment. Checks for violations within-test and within-control. Different controls on same test and then different tests on same control. Applied within-run and across-runs.
VS / VT / VC	Combination VS/VT/VC assessment. Checks for violations within-series, within-test and within-control. Same control on same test; then same test on different controls; and, then different test(s) on same control. Applied within-run and across-runs.

Rules are enabled or disabled by moving the cursor into the Enabled column to a position opposite the rule to be changed. Press **<Spacebar>** to cycle through the options available for each rule. Once the desired option is displayed, move the cursor to a new position or press **<Enter>** or **<Esc>** to complete the selection process.

Once a rule has been enabled by selecting VS, VT, VC or one of the available combinations, the selected definition will be transferred to all Controls subsequently defined. Controls defined previously using an earlier set of default definitions will not be changed to the new settings.

Examples of VS, VT and VC violations for each of the rules are presented in section 20.5.

20.1.1.3 The "**Alarm**" column is used to enable or disable an audiovisual alert when a rule violation occurs.

"NO" indicates that even in the event a rule violation on an enabled rule occurs, no alarm will sound or error message will be displayed. "QC Er" will be displayed on the Status bar. Any violation of an enabled rule will be noted in the QC report. "NO" should be used for those rules that although you want to know that the rule has been violated, the rule is not being used as a run stopper.

"YES" indicates that in the event a rule violation occurs, an alarm will sound and an error message indicating which rule or rules have been violated will be displayed. "YES" should be reserved for those rules that are being used as run stoppers.

[Q.C. Error]

```
The control Level 1 assayed on PT-O
Has violated the Westgard rule(s) VS:2-2s, VS:1-3s, VS:1-2s
```

To change the Alarm setting from NO to YES, move the cursor over the "NO" and press **<y><Enter>**. To change the Alarm setting from YES to NO, move the cursor over the "YES" and press **<n><Enter>**. The <up or down arrow keys> may also be used to complete the setting change.

The "Alarm" setting may be used to determine the sensitivity of the rules. The purpose in using a multirule system is to maximize error detection and minimize false rejections. The 4-1s and 10-m rules are sensitive indicators of small changes in the accuracy of a procedure. These changes may not be significant enough to reject a run but may indicate that inspection of the analytical process should be performed to determine why the change has occurred. Early warning of small changes will allow opportunity to correct the problem before the changes are large enough to cause run rejection.[4] Possible approaches to setting the sensitivity of the rules are presented in section 20.4.

20.1.1.4 The "**Option**" column is used to set alternative decision limits for each rule. The "Opt. value" column is used to set the limit values for use with the "Pkg.Lim" or "%Target" options. Realizing that some laboratories may want to evaluate QC data using different decision criteria than those encompassed by the traditional Westgard Multirules, the AMAX 200 QC program has been designed to be flexible. Eight rules are available. Each rule has at least one option with some having as many as six.

Each rule has a default decision criterion which matches the name in the Rule column. Although the decision criterion may be changed, the name may not. The name will not change to match the criterion option selected. For example: Rule 1-2s has a default decision limit of > ± 2 SD. If the option of %Target with an Option value of 5% is selected, the decision limit used for evaluation will be > ± 5% of the target value but the violation name displayed on all reports will be 1-2s.

Press **<spacebar>** to cycle through the options available for each rule. Once the desired option is displayed, move the cursor to a new position or press **<Enter>** or **<Esc>** to complete the selection process. The <arrow keys> may also be used to complete the selection process.

When the "Option" is set to "**none**", the default criterion will be used. The "Option value" setting is "**0**". For example: The decision criterion for Rule 1-2s with the "Option" set to "none" and the "Option value" set to "0", is one control result > ± 2 SD. No entry into the "Option value" column is necessary. Any numbers entered into the "Option value" column will be ignored. The rule "Name" will match the decision criterion.

When the "Option" is set to "**1sd, 2sd, 3sd or 4sd**", the selected option will replace the default criterion. The evaluation will be done by referring to the 2SD entry in the "Control Definition" file (or 2SD value for the selected target) and making calculations as appropriate. The "Option value" setting is "**0**". For example: The decision criterion for Rule 2-2s with the "Option" set to "3sd" and the "Option value" set to "0", is two consecutive control results > ± 3 SD. No entry into the "Option value" column is necessary. Any numbers entered into the "Option value" column will be ignored. The rule "Name" will not match the decision criterion. Note that there is a redundancy associated with each of the rules having these options. For example: One of the options for the 2-2s rule is 2sd. This is the same as the default criterion. It does not have to be selected. Setting the option to "none" or "2sd" has the same result.

When the "Option" is set to "**Pkg.Lim.**" (Package Limit), the evaluation will be done using the "Min/Max" value entries or the "Option value" entry rather than referring to the 2SD entry in the "Control Definition" file (or selected target 2SD). The "Pkg.Lim." option is useful when changing lot numbers or evaluating a new control material or any other time the evaluation is to be done using a numerical value other than SD. Because the selections made in the "Westgard rule setup" screen are "default" settings that will be applied to all tests on new controls and because "package limit" values refer to specific tests, no entry into the "Option value" is really appropriate. The "Option value" setting is more appropriately set in the "Control Definition" or "QC File directory" list.

20.1.2
20.2.2

When the "Option" is set to "**%Target**", the evaluation will be done using the "Option value" entry rather than referring to the 2SD entry in the "Control Definition" file (or selected target 2SD). The value is entered as the desired percent deviation from the mean. The "%Target" option is useful if using "% error allowed" rather than basing the evaluation on SD. Because the selections made in the "Westgard rule setup" screen are "default" settings that will be applied to all tests on new controls and because % allowable error is typically test specific, no entry into the "Option value" is really appropriate. Unless the same percent deviation is to be applied to the majority of tests, the "Option value" setting is more appropriately set in the "Control Definition" or "QC File directory" list.

20.1.2
20.2

The "Option" available for rule 4-1s, 10-m and 7-t is "**Alternate**". The default criterion for each rule is the original Westgard rule. The "alternate" evaluation is

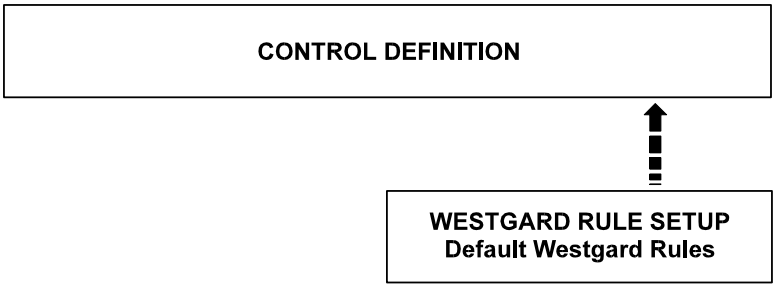
more stringent than the original Westgard definition in that one of the values in the evaluation series must be > ± 2SD from the mean. For example: When 4-1s is set to "None", the default criterion that four consecutive control results are > ± 1 SD from the mean in the same direction is used. When 4-1s option is set to "Alternate", the criterion that four consecutive control results are > ± 1 SD and one of those results is > ± 2 SD is used.

Option and Option Value Examples				
Rule	**Option Setting**	**Option Value**	**Evaluation Criteria**	**Violation Report**
1-2s	None	0	One control result > ± 2 SD from target.	1-2s
1-2s	2sd	0	One control result > ± 2 SD from target.	1-2s
1-2s	3sd	0	One control result > ± 3 SD from target.	1-2s
1-2s	Pkg.Lim.	4.5	One control result > ± 4.5 M.U. from target.	1-2s
1-2s	%Target	3	One control result > ± 3% from target.	1-2s
4-1s	None	n.a.	Four control results > ± 1SD from target in the same direction.	4-1s
4-1s	Alternate	n.a.	Four control results > ± 1SD from target in the same direction and at least one result is > ± 2SD from the target.	4-1s

Once all the rules have been defined, press **<Esc>** to store the default rule setup and to exit the screen. The rule setup will be transferred to every test on a newly defined control.

20.1.1.5 Flowchart of Information Transfer

The "Westgard Definitions" are the rules setup that is transferred to every test on newly defined controls. The "Westgard Def" menu is used to define these "default" evaluation rules. If the majority of tests are evaluated using the same rules, setting the default rules will save time when defining the evaluation criteria for each test. Only the exceptions to the rules will require changing rather than having to set all rules for every test.



20.1.2 Controls

Password security system = unrestricted
PIN level accesses = 2 (full), 1 (full) and 0 (prohibited)

The Controls menu is used to define the identification information and evaluation values for each control material.

To open the "Control list" selection window, press **<c>** or move the cursor to "**Controls**" and press **<Enter>**. The "Control list" will be displayed.

[Control list]

ID Code	Control	Expiration
QC1	Level 1	01-01-00
QC2	Level 2	01-01-99
QC3	Level 3	12-31-01
ACN	Accutrol Normal	06-30-00
ACA	Accutrol Abnormal	09-30-99
FIBLO	Fibrinogen Low	02-29-04

The "Control list" is a listing of all defined controls and is used to add new control definitions or to select a control for editing.

NOTE: The ID Code for QC data transferred from version 3.1.13 AMAX software will be QC1, QC2 and QC3. The control name for transferred files will be Level 1, Level 2 and Level 3. The expiration date for these files will be whatever was entered during "Extracting QC information" portion of the installation of the 3.1.14 software.

20.1.2.1 Addition of a New Control

<Q.C.><Q.C.Setup><Controls>

To define a new control, move the cursor to an **<empty position>** in the "Control list" and press **<Enter>**. The "Control definition" dialog window opens. Move through the fields using the arrow keys.

[Control definition]

F9:Delete **F10:Undo**

```
ID Code    :
Name  :
Manufact.  :
Lot No.    :
Expiration : 00-00-00
```

	----Assigned Values----					----Westgard Rules---
Test	M.U.	Target	2SD	Min	Max	
PTO	???	0		0	0	1-3s,2-2s,R-4s,4-1s
PTTM	???	0		0	0	1-3s,2-2s,R-4s,4-1s
FIB	???	0		0	0	1-3s,2-2s,R-4s,4-1s
TTM	???	0		0	0	1-3s,2-2s,R-4s,4-1s
F8	???	0		0	0	1-3s,2-2s,R-4s,4-1s
F9	???	0		0	0	1-3s,2-2s,R-4s,4-1s
DRVVT	???	0		0	0	1-3s,2-2s,R-4s,4-1s

[<Esc> to finish]

a. ID Code: Entry into the "ID Code" field is mandatory. Type in an alphanumeric sequence that will identify the control material (character limit = 18). It may be any unique alphanumeric designation that will be readily recognizable and easy for anyone in the laboratory to remember. The same ID code may not be used for more than one control material. An error message will be displayed if a duplicate ID code is entered. The ID code is what the AMAX uses for identification. It is used to preface entry of QC samples when ordering tests. A sequence should be selected that will never be a Patient ID or any bar code that might be used for patient samples.

b. Name: Entry into the "Name" field is mandatory. Type in an alphanumeric sequence that will identify the control material (character limit = 20). The Name serves to fully identify the control material. Duplicate names will not be disallowed.

c. Manufact.: Entry into the "Manufact." field is optional. Type in the Manufacturer of the control material (character limit = 20).

d. Lot No: Entry into the "Lot No" field is mandatory. Type in the Lot Number of the control material (character limit = 20).

e. Expiration: Entry into the "Expiration" field is mandatory. Type in the expiration date of the control material (MM-DD-YY)(MM/DD/YY may also be entered but will require either <arrow><arrow> or <Enter><arrow> to leave the field.)

Once the control identification features have been defined, the evaluation criteria are defined. Use the **<down arrow>** key or the **<Enter>** key, to move the cursor into the evaluation information fields.

Control Definition – Evaluation Information Fields	
Field	**Definition**
Test	Automatic instrument entry. The "Test" column contains all of the tests programmed on the AMAX. The order of appearance in the list is the order that they appear in the Test List. All programmed tests are candidates for inclusion on any control material.
M.U.	Measuring Unit. Defines the type of data reduction to use for the analysis of QC data. The options available for each test are all the Measuring Unit definitions (up to 3) included in the Data Reduction section of the Test Parameters. Use the <space bar> to cycle through options. Although not a mandatory entry field, if an option is not chosen (left at ???), QC results for that test will not be processed.
Target	Mandatory entry. Mean value. Enter value in the measuring unit selected (character limit = 7). The target is the base value used to calculate all limits.
2SD	Mandatory entry. Used for SD-based evaluation of data. Even if an optional value is to be used for data evaluation, the 2SD field must be completed (character limit = 7; decimal positions will be truncated to 2). The 2SD entry is used in the construction of the multirule-charts. The 2-SD entry is always used to derive the chart limits even when using the "Pkg.Lim." and "%Target" options.

Control Definition – Evaluation Information Fields	
Field	**Definition**
Min and Max	Optional entries (character limit = 7; decimal positions will be truncated to 2). The "Min/Max" values are used for evaluation only when the "Pkg.Lim" option is selected. For SD based evaluations, "Min/Max" is usually used to define "panic" values or limits other than those defined by the evaluation rule. Another potential use is for entry of Medical Decision Limits.
Westgard Rules	The "default" Westgard rules as setup in "Westgard rule setup". All newly defined controls will initially contain the current "default" setup. The rule setup for each test may be edited. As soon as the cursor enters the target field, a function key is added at the top of the screen. <F2:Westgard rule setup> is used to individually edit the Westgard rule setup for each test.

f. After leaving the identification fields, the cursor will be positioned in the M.U. field of Test 1. Move the cursor down the M.U. column to a position opposite the first test to be defined on the new control.

g. Use the **<space bar>** to cycle through the measuring unit options. Select the unit to be used for data evaluation. Complete the selection by pressing **<right arrow>** or **<Enter>.** Note that if no option is selected (???), the results will not be entered into the QC File or be displayed on the QC chart. Unless a selection is chosen, the option will automatically cycle to the first data reduction option when the field is next accessed by an arrow key.

h. Enter the Mean value into the "Target" field. When first setting up a control, the statistical mean may not be known. Enter a best estimate value. The value may be edited later when the calculated statistical mean is known. The target value entered is transferred to the QC charts and is used as the base value for statistical analysis. Complete the entry by pressing **<Enter>**.

i. Enter the 2SD value into the "2SD" field. When first setting up a control, the statistical SD may not be known. Enter a best estimate value. The value may be edited later when the calculated statistical 2SD is known. The 2SD value is used to construct the limits on the QC charts and is used as the base value for evaluations based on SD. Note that the chart limits are always derived from the 2SD entry, even if the evaluation option is set to "Pkg. Lim." or "%Target" and an "Option Value" has been set. If it is desirable to have the chart limits reflect the Package Limits or %Target setting, the 2SD limit should be set to appropriately reflect the Option Value setting. Complete the entry by pressing **<Enter>**.

Package Limit and % Target Setting Examples							
Option Setting	**Assigned Range or Mean**	**Target Setting**	**Opt.Value Setting**	**2SD Setting**	**Chart ± 1SD Lines**	**Chart ± 2SD Lines**	**Chart Top And BottomLimits**
Pkg.Lim.	25-35	30	5	5	2.5	5	7.5
%Target	30	30	3	0.9 (30 x 0.03)	0.45 (1.5%)	0.9 (3%)	1.35 (4.5%)

As soon as the 2SD entry is complete, all fields for that test will be yellow indicating that all mandatory entries have been completed. All fields on fully

defined tests will be yellow. Undefined or partially defined tests will have yellow Test and M.U. fields but the remaining fields will be blue.

j. Enter limits as appropriate into the "Min" and "Max" fields. Complete the entry by pressing **<Enter>** or **<up** or **down arrows>**. The "Min/Max" values are used for evaluation only when the "Pkg.Lim" option is selected. For SD based evaluations, "Min/Max" is usually used to define "panic" values or limits other than those defined by the evaluation rule. They do not function in the evaluation of data or in chart construction.

k. The Westgard Rules for each test may be edited by pressing **<F2>** while the cursor is in the "Target", "2SD", "Min" or "Max" fields. The "Westgard rule setup" selection window will open and each rule may be set as appropriate to the specific test being defined.

20.1.1

l. Continue entering Assigned Values and editing the Westgard Rules for each test to be defined for the control material.

m. All control definition information will be transferred to each newly created QC File.

20.1.2.2 To Modify a Previously Defined Control

<Q.C.><Q.C.Setup><Controls>

Because there are many referrals to QC Files and QC Charts, it is recommended that these sections be read prior to modifying a previously defined control.

20.2
20.3

To modify a previously defined control, move the cursor to the **<desired control>** in the "Control list" and press **<Enter>**. The "Control definition" dialog window opens.

CONTROL DEFINITION COLOR CODING			
Test	**M.U.**	**Values/Rules**	**Interpretation**
Yellow	Yellow	Blue	Undefined or partially defined
Yellow	Yellow	Yellow	Defined (Target and 2SD)
Red	Yellow	Yellow	Defined and has active QC File
Blue	Blue	Yellow	Previously defined but Test has subsequently been deleted from Test List
Blue	Blue	Blue	Previously defined but Test Code has subsequently been changed in Test Definition

The process for modifying a control definition is the same as for defining a new control. Only the consequences are different.

ATTENTION!
Do not change the ID Code, Name or M.U. unless all QC Files created using the "old" ID Code, Name or M.U. have been closed.

If you decide at any point in the editing session that you do not want to make any of the changes, press **<F10>**. The "F10:Undo" procedure must be performed

prior to exiting the "Control definition" window. Once the window has been exited, the changes will be in effect.

a. The **ID Code** should not be modified unless all QC Files for that control have been closed. The Test Code for open files is displayed in red. Closed or inactive files are displayed in yellow. An ID Code change does not transfer to previously created files. The AMAX uses the ID Code to identify and associate data and files with each other. If QC files for that control are still active when the ID Code is changed, the QC charts for previously defined files no longer have a control definition file to refer back to for manually assigned values. The old ID Code must still be used to add data to previously created files. Assigned values will be fixed at the settings in use prior to the change. The change in ID Code will be transferred to all newly created QC Files.

b. The **Name** should not be modified unless all QC Files for that control have been closed. The Test Code for open files is displayed in red. Closed or inactive files are displayed in yellow. The Name change does not transfer to previously created files. All pre-existent files retain the original control definition Name. The change in Name will be transferred to all newly created QC Files.

c. The **Manufact.** field is an information only entry and is not used by the program. Any change will only be reflected in the Control Definition.

d. No permanent change can be made to the **Lot No.** Any change made will be temporary but the date of attempted change will be noted in the QC File Descripton. The original information will be restored after screen exit.

e. No permanent change can be made to the **Expiration date**. Any change made will be temporary. The original information will be restored after screen exit.

f. **Measuring Units (M.U.)** should not be modified unless the QC File for that test has been closed. The Test Code for open files is displayed in red. Closed or inactive files are displayed in yellow. Data is collected and evaluated using the M.U. current in the Control Definition. Although the M.U. has been changed, the unit designation in the QC File will not be updated. Example: Fibrinogen data reduction (Test Parameters, Data Reduction) is set to "C" (curve, mg/dL) and "T" (sec). If the original M.U. for fibrinogen was set to mg/dL, the data is collected as mg/dL. The seconds are not collected and stored in the QC File. If the M.U. is changed to sec, data from that point on will be collected as seconds. The data in the file will be mixed mg/dL (pre-change) and sec (post-change). The unit indication for fibrinogen in the QC File will be mg/dL.

   If the M.U. is changed to "???", although the QC testing for that test may be run, the data will not be processed.

   Any change in M.U. for a test will be displayed at the top of the QC chart as the operative unit for data collected after the change. Any change in M.U. for a test will be transferred to newly created QC Files.

g. Any change to the **Target** and/or **2SD** is reflected in the QC Chart. The QC charts and the Target/2SD fields in the Control Definition are linked. The QC charts derive the manual target (Man Mean) and 2SD assignment value (Man 2SD) from the Control Definition. Any changes made to the Target

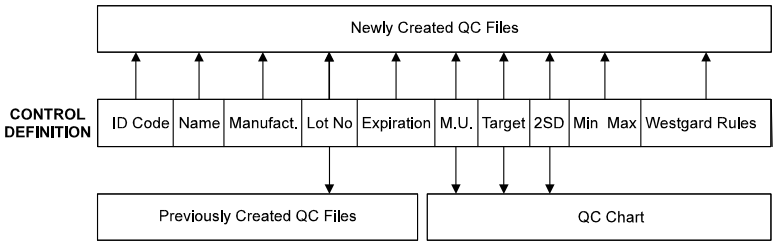
and/or 2SD value in the Control Definition will be transferred to the active QC chart(s) and to the statistical/evaluation registers. At the beginning of every run, the operative values for each control are updated assuring that the evaluations will be done using the most current mean and SD information.

h. If the **Target** and/or **2SD** for any test with an active file are changed to 0 and the target is set to manual (Man), the associated QC chart will display "No Mean or SD". If there were values in the chart, when the full size chart is selected the Manual target and/or 2SD entry will be 0. Reentry of the target and/or 2SD value in the Control Definition will return the chart to normal appearance.

i. The **Min** and **Max** values are used only if the "Pkg.Lim" option has been selected. For all other evaluations options, the Min/Max values have no influence on data collection or evaluation and are information only values, not operative values. Any changes will only be observed in the Control Definition file.

j. Changes to the **Control Definition Westgard Rules** will not be transferred to previously created QC files. Changing the Control Definition Westgard Rules for any test will not change the way the test is evaluated in previously created QC files. Any change in the Westgard Rules for a test will be transferred to newly created QC Files for that test.

The data transfer from the Control Definition to the QC Files and QC chart are shown graphically below:



20.1.2.3 To Delete a Control

<Q.C.><Q.C.Setup><Controls>

To delete a control, move the cursor to the **<desired control>** in the "Control list" and press **<Enter>**. The "Control definition" dialog window opens.

The Test Code for open active files is displayed in red. Closed or inactive files are displayed in yellow. If there are any open files, due consideration should be given prior to deleting the control. If the control is deleted, all open files will be automatically closed and the "End date" will indicate today's date. All associated QC charts will be closed. If reactivation of these files is anticipated later, a copy of the Control Definition should be made using <Print Scrn>. Be sure to include all pages of the test listings.

If the decision is made to delete the control, with the cursor in one of the control information fields (ID Code, etc.), press **<F9>**.

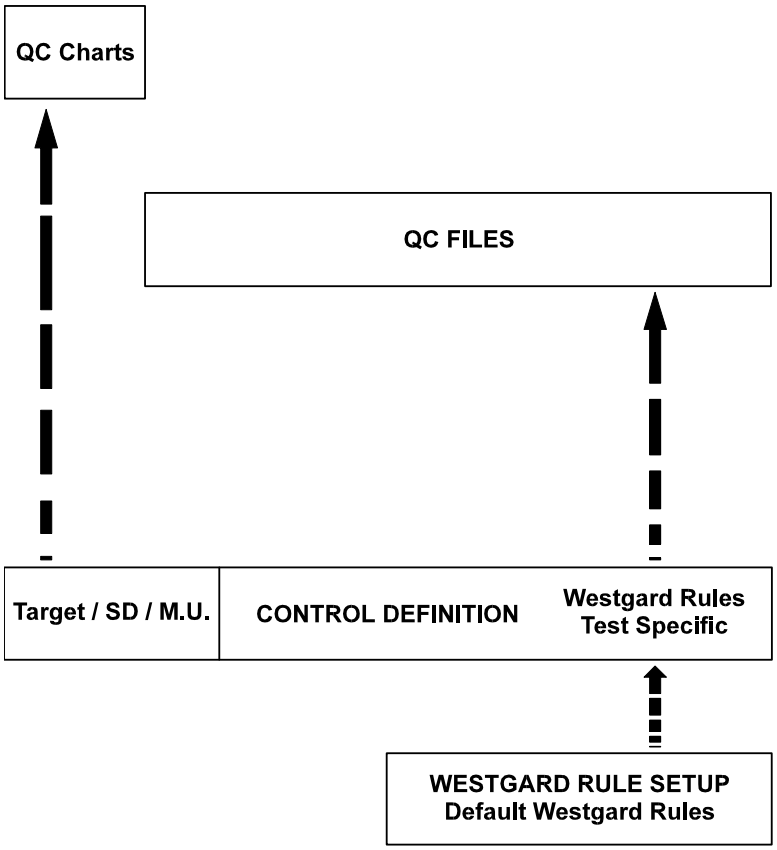
```
Delete Control

Do you want to delete? NO
```

Confirm the deletion with **<y><Enter>**. Deny deletion with **<Enter>** or **<n><Enter>**.

NOTE: If at the time of the deletion request, the cursor was in one of the Assigned Value fields, deny deletion with **<Enter><Esc>**. Any observed transposition of information prior to escaping will be temporary. Do not try to fix anything. After escaping and returning to the definition, all information will be as before the deletion denial.

20.1.2.4 Flowchart of Information Transfer

The Control definition file contains the control identification information (ID Code, Name, etc.) and is used to define the Measuring Units (M.U.) to be used for evaluation, set the manual Target, 2SD, low (Min) and high (Max) values. It is also used to set the Westgard rules to be specific for each test if different from the default Westgard definition defined in the Westgard rule set up. When a QC File for a test is created, all information from the Control Definition for that test is transferred to the newly created file. The target, 2SD and M.U. values are linked to the manual target field in the QC Chart. Any adjustments in the manually assigned target and 2SD values are made in the Control Definition files.



The information stored in the Control Definition for each test is transferred to a newly created QC file for each test. Note that there is no backward flow of Westgard rule setup from the Control Definition to the default Westgard Rule Setup. Changes made to the Westgard rules in Control Definition will not be reflected in the default setup. The assigned values (Target, 2SD and M.U.) are directly linked to the QC chart. Any changes to the target, 2SD values or to the M.U. will be active the next time the test is run.

20.2 QC Files

The QC Files menus are used to open and close test QC files and perform several file maintenance functions.

<Q.C.><Q.C. Files><Enter>. To open the "Q.C. Files" menu, press **<f>** or move the cursor to "**Q.C. Files**" and press **<Enter>**. The "Q.C. Files" submenus available are displayed.

Create	Section 20.2.1
List	Section 20.2.2
Export	Section 20.2.3
Backup	Section 20.2.4
Restore	Section 20.2.5
Delete	Section 20.2.6

20.2.1 Create

Password security system = full access
PIN level accesses = 2 (full), 1 (full) and 0 (prohibited).

The "Create" menu is used to activate (open) and inactivate (close) QC Files for each test on each control material. A QC File for a test may be opened or closed at any time. A test may have an open QC File on multiple control materials. One control material may have only one open file for any available test.

Under normal circumstances, a QC File for every test will need to be created with a new lot number of control material. Depending on the lot-to-lot variability of reagents, a new file may be needed whenever the reagent(s) lot number changes.

Prior to creating a QC File, the corresponding test must have been defined in the Control Definition.

20.1.2

<Q.C.><Q.C. File>. To open the "Create" menu, press **<c>** or move the cursor to **<Create>** and press **<Enter>**. The "Create Q.C. File list is displayed. The listing contains all currently defined control materials.

[Create Q.C. File]

ID Code	Control	Expiration
QC1	Level 1	01-01-00
QC2	Level 2	02-31-02
QC3	Level 3	02-29-04
ACN	Accutrol Normal	02-01-00
ACA	Accutrol Abnormal	01-12-99
FIB LO	Fibrinogen Low	06-30-99

Move the cursor to the control material to which the new test QC File is to be added and press **<Enter>**. The "Create Q.C. File" dialog window will open.

The file contains information transferred from the corresponding Control Definition for the selected control material.

[Create Q.C. File]

```
ID Code  :QC1
Name     :Level 1
Manufact.:Sigma
Lot No.  :12345
Expiration    :01-01-00

              -----Assigned Values-----      ----Westgard Rules---
Test  M.U.    Target  2SD     Min   Max
PTO   Sec     12.2    0.98    10    15       1-3s,2-2s,R-4s,4-1s
PTTM  Sec     26.9    2.15    20    35       1-3s,2-3s,R-4s,4-1s
FIB   mg/dL   254     25.4    200   300      1-3s,2-2s,R-4s,4-1s
TTM   Sec     12.8    2.04    8     16       1-3s,2-2s
F8    ???     0       0       0     0        1-3s,2-2s
F9    ???     0       0       0     0        1-3s,2-2s
DRVVT ???     0       0       0     0        1-3s,2-2s
```

Test QC Files that are defined and active (open) are all red. Files that are defined but are inactive (closed) are yellow. The Test and M.U. columns of an undefined or incompletely defined test are yellow while the Assigned Values and Westgard Rules areas are blue.

20.2.1.1 To create a file on an **inactive (all yellow) test**, move the cursor to the **<desired test>** and press **<Enter>**.

[Create Q.C. File]

```
Create a new file? NO
```

Confirm creation with **<y><Enter>.** Deny creation with **<Enter>**.

With confirmation, the information transferred from the Control Definition file and the lot numbers of the reagents associated with the test are displayed.

[Create new QC File]

```
F9:Create

Control: QC1                          Target:  254
         Level 1                      +/-:     25.4
                                      Low:     200
Test:    FIB                          High:    300
         Fibrinogen-Clauss
Description:
Level 1 Lot No:123
Imidazole Buffer Lot No:68H6136
Thrombin Lot No:088H6196
```

The Control lot number and reagent name(s) and lot number(s) may be edited as appropriate.

When the appropriate editing is completed, press **<F9>.** "Confirm file creation:YES" is displayed in the bottom of the box. Press **<Enter>** to confirm. Although easily forgotten, this step must be done before the file will be created. Press **<n><Enter><Esc>** to deny creation.

As soon as the file creation has been confirmed, all information for that test will be red.

20.2.1.2 To create a new file on an **active (all red) test**, move the cursor to the **<desired test>** and press **<Enter>**. Before a new file may be created, the currently active file must be closed.

[Create Q.C. File]

```
Close current file? NO
```

To confirm closing, press **<y><Enter>**. To deny closing, press **<Enter>**.

As soon as the file is closed, all information for that test will be yellow. A new file for that test may be created as described above (20.1.1.1).

20.2.1.3 Before a new file may be created on **an undefined or partially defined test**, the test must have been previously completely defined in Definition Control.

20.1.2

If an undefined or partially defined test is selected an error screen will be displayed.

[Error]

```
The selected item is not completely defined !
```

Press **<any key>** to clear the error message. Exit the to the main Q.C. menu by pressing **<Esc>** four times. Go to **<Q.C. Setup><Controls><appropriate control><Enter>** and complete entry into all mandatory fields.

20.1.2

20.2.1.4 Reactivation of Previously Closed Files (all yellow)

<Q.C.><Q.C. Files><Create><control associated with the test to be reactivated><Enter>.

ATTENTION!

It is recommended that a file only be reactivated back into the original control with which it was associated. A reactivated file always keeps its original control name and other information transferred from the original Control Definition. Although the program will allow reactivation of a file into a control with a different ID Code and control name, the file will not derive mean, SD or other evaluation values from the unmatched control file. The control name, test name and measuring unit displayed on the QC chart will be that of the original control definition.

Move the cursor to the **<desired test>** (must be all yellow) and press **<Enter>**. When the "Create a new file? NO" box is displayed, press **<Enter>**.

[Create Q.C. File]

```
Create a new file? NO
```

<Enter>

[Create Q.C. File]

```
Pick an existing file ? NO
```

To confirm the reactivation, press **<y><Enter>**. To deny, press **<Enter>**.

Denying the reactivation returns to the "Create Q.C. File" dialog window. Acceptance brings up the Q.C. File Directory that contains a listing of all QC files currently stored in the Q.C. File.

[QC File Directory]

F2:Westgard rule setup F5:Description

ID Code	Control	Test	Start date	End date
QC1	Level 1	PTT(Sec)	01/01/1999	
QC2	Level 2	PTT(Sec)	02-02-1999	
QC3	Level 3	FIB(mg/dL)	09-30-1998	02-28-1999
ACN	Accutrol Normal	F8(%A)	02-05-1999	
ACA	Accutrol Abnormal	F8(%A)	02-05-1999	
FIB LO	Fibrinogen Low	FIB(mg/dL)	09-30-1998	
QC1	Level 1	FIB(mg/dL)	02-28-1999	
ACN	Accutrol Normal	AT(%A)	03/18/1999	

Files that are active (in use) are displayed in blue. Files that are inactive (closed) are displayed in yellow. If the Test Code is flashing, either the test has been deleted from the Test List or the Test Code in the Test Parameter Description has been changed. Only files that are inactive (yellow) may be chosen for reactivation. The ID Code, Control Name, Test and measuring unit being used for evaluation, the date the file for that test was opened (Start date) and, if appropriate, the date the file for that test was closed (End date) are displayed. A file eligible for reactivation will be yellow and always have both a Start and an End date.

Prior to completion of the reactivation process, the Description of the file(s) may be viewed by pressing **<F5>**.

20.1.1

Prior to completion of the reactivation process, the Westgard Rules that were active when the file was last used may be viewed and changed if desired. Press **<F2>** to open the "Westgard rule setup" dialog window. Any of the setup may be altered as desired. Any changes to the evaluation criteria will become the current evaluation procedure when QC is run on the selected test.

When ready to complete the reactivation process, move the cursor to the test to be reactivated, press **<Enter>**.

The display returns to the "Create Q.C. File" selection window. The reactivated file is displayed in red and is now available for use. Once reactivated, the file will display in QC Charts. The control name, test name and measuring unit displayed will be those of the original control definition. Points can be added to the reactivated file by ordering the test using the ID code of the control that was selected during the "Pick an existing file" process. Manual mean and 2sd information will be interactive only if the file has been reactivated into the original control definition.

20.2.2 List

Password security system = full access
Security Level accesses = 2 (full), 1 (full) and 0 (full).

The "List" contains a listing of all the Q.C. Files available for use. These files may be either active (open) or inactive (closed). Open files are actively in use. Closed files have been used in the past but are no longer actively in use. Closed files may be reactivated.

20.1.2.4

<Q.C.><Q.C. File>. To open the "List" menu, press **<l>** or move the cursor to **<List>** and press **<Enter>**. The "QC File Directory" is displayed.

[QC File Directory]

F2:Westgard rule setup F5:Description

ID Code	Control	Test	Start date	End date
QC1	Level 1	PTT(Sec)	01/01/1999	
QC2	Level 2	PTT(Sec)	02-02-1999	
QC3	Level 3	FIB(mg/dL)	09-30-1998	02-28-1999
ACN	Accutrol Normal	F8(%A)	02-05-1999	
ACA	Accutrol Abnormal	F8(%A)	02-05-1999	
FIB LO	Fibrinogen Low	FIB(mg/dL)	09-30-1998	
QC1	Level 1	FIB(mg/dL)	02-28-1999	
ACN	Accutrol Normal	AT(%A)	03/18/1999	

Files that are active (in use) are displayed in red. Files that are inactive (closed) are displayed in yellow. If the Test Code for any test is flashing, the test associated with that file has been deleted from the test programming. The ID Code, Control Name, Test and measuring unit being used for evaluation, the date the file for that test was opened (Start date) and, if appropriate, the date the file for that test was closed (End date) are displayed.

With the cursor over a selected test, the Description of that file may be viewed by pressing **<F5>**.

[QC file description]

```
Accutrol Normal Lot No:68H6164
Imidazole Buffer Lot No:019H6043
F7D Lot No:118H6356
ThromboMAX Lot No:48H6215 changed on 02-05-1999
```

For security Levels 1 and 2, the Westgard rule setup may be viewed and edited. Press **<F2>** to open the "Westgard rule setup" dialog window. There are occasions when it will be desirable to temporarily change the rule evaluation protocol for a test. An example would be at a change in reagent lot number. Normally the test is

being run with the 1-3s, 2-2s and R-4s rules enabled and set to alarm when violations occur. 4-1s and 10-m are enabled but not set to alarm. When a reagent lot number changes, a change to increase the sensitivity of error detection may be achieved by changing the alarm status to on for the 4-1s and 10-m rules. The operator will be alerted to any shift that occurs because of the lot number change. Any of the setup may be altered as desired. Any changes to the evaluation criteria will become the current evaluation procedure when QC is run on the selected test. The evaluation registers are updated at the beginning of every run.

20.2.3 Export

Password security system = full access
Security Level accesses = 2 (full), 1 (full) and 0 (full)

The AMAX 200*AMAX* QC Program has been designed to be able to electronically transfer QC data into the Computrol℠ QC program. Computrol℠ is an external QC program. The Export function gives the laboratory the opportunity to participate in an external quality control program that will give the participant laboratories pertinent inter- and intra-laboratory comparison information.

Direct electronic data transfer is not currently available. Since it is not available, the Export function will not be discussed further.

Manual submission of QC data generated on the AMAX is available. Telephone Sigma Diagnostics Technical Services for more information (1-800-325-0250).

20.2.4 Backup

Password security system = full access
Security Level accesses = 2 (full), 1 (full) and 0 (full)

The “Backup” function is used to archive QC data onto a 1.4-KB floppy disc. Each file is backed up individually.

<Q.C.><Q.C. File>. To open the “Backup” menu, press **<b>** or move the cursor to **<Backup>** and press **<Enter>**. The “QC File Directory” is displayed.

[QC File Directory]

F2:Westgard rule setup F5:Description

ID Code	Control	Test	Start date	End date
QC1	Level 1	PTT(Sec)	01/01/1999	
QC2	Level 2	PTT(Sec)	02-02-1999	
QC3	Level 3	FIB(mg/dL)	09-30-1998	02-28-1999
ACN	Accutrol Normal	F8(%A)	02-05-1999	
ACA	Accutrol Abnormal	F8(%A)	02-05-1999	
FIB LO	Fibrinogen Low	FIB(mg/dL)	09-30-1998	
QC1	Level 1	FIB(mg/dL)	02-28-1999	
ACN	Accutrol Normal	AT(%A)	03/18/1999	

Files that are active (in use) are displayed in red. Files that are inactive (closed) are displayed in yellow. A flashing test code indicates that either the Test Code for the test has been changed or the test has been deleted from the Test List. Any file may be backed up regardless of its activity status.

The File Description may be viewed. Press **<F5>** to open the "QC file description" window.

For security Levels 1 and 2, the Westgard rule setup may be viewed and edited. Press **<F2>** to open the "Westgard rule setup" dialog window. Although the rules may be edited, it should not be done on a file being backed up except under extenuating circumstances. The backup file will contain the edited rule evaluation protocol that may not accurately reflect how the data was collected.

When ready to perform the backup, place a 1.44 MB floppy disc into Drive A. With a disc in Drive A, move the cursor to the **<desired file>** and press **<Enter>**. If there is no disc in Drive A, a disc write error message will display at the top of the screen.

The selected QC File is copied onto the disc in Drive A. Note that each file selected for backup creates a new copy. If the backup session is to include multiple files, it is helpful to keep track of which files have been backed up. This will avoid unnecessary duplication of copied files on the backup disc.

20.2.5 Restore

Password security system = full access
PIN level accesses = 2 (full), 1 (full) and 0 (prohibited)

Once a QC File has been backed up, it may be restored. There are a number of reasons to backup QC files. They may be restored and used for historical comparison with current files. They may be restored and put back into active use. In case of disaster, restored files will avert loss of all QC data.

<Q.C.><Q.C. File>. Place a backup disc into Drive A. Initiate the "Restore" function by pressing **<r>** or moving the cursor to **<Restore>** followed by **<Enter>**. A "QC File Directory" window is displayed. If there is no disc in Drive A or if there are no backup files on the disc, a "No files found!" message will be displayed in an empty QC File Directory window.

The listing contains all of the files that have been backed up onto the disc. Since all backup files are inactive, all files are yellow. An ID Code, Control name, Test, Start Date and End date is listed for each file. If there are files on the disc associated with tests that have been deleted from the test programming, the Test Code and Units in the Test column for that test will be flashing. The "Start date" is the date the file was originally created. The "End date" is the date the file was backed up. Files are copied onto the backup disc consecutively. The most recently backed up files are at the end of the listing.

The File Description for any file may be viewed. Move the cursor to the **<selected test file>** and press **<F5>** to open the "QC file description" window.

When ready to restore, move the cursor to the **<desired file>** and press **<Enter>**.

The file is restored to the active QC File Directory where it may be reactivated. Note that if the control that was associated with a restored file has been deleted, a control with matching ID Code and Name must be defined and the test to be restored must be defined before it may be reactivated. Also, note that if a flashing test is restored, the test will appear at the bottom of the test listing. The test code and M.U. will be blue.

20.2.6 Delete

Password security system = full access
PIN level accesses = 2 (full), 1 (full) and 0 (prohibited)

The “Delete” function is a file maintenance function used to clean out any files that are no longer needed in the active file directory. Over time, the QC File Directory may become cluttered with files that have long been inactive. Backup of any potentially useful files is recommended prior to deleting. Once deleted, a file may only be retrieved using the Restore function. If there is any question that the file might be needed in the future, make a backup.

<Q.C.><Q.C. File>. To initiate the “Delete” function, press **<d>** or move the cursor to **<Delete>** and press **<Enter>**. The “QC File Directory” is displayed.

Files that are active (in use) are displayed in blue. Files that are inactive (closed) are displayed in yellow. Only files that are inactive (yellow) may be chosen for deletion. The ID Code, Control Name, Test and measuring unit being used for evaluation, the date the file for that test was opened (Start date) and, if appropriate, the date the file for that test was closed (End date) are displayed. A file eligible for deletion will be yellow and always have both a Start and an End date.

Once it has been ascertained that the test file may be safely deleted, move the cursor to the **<doomed file>** and press **<Enter>**.

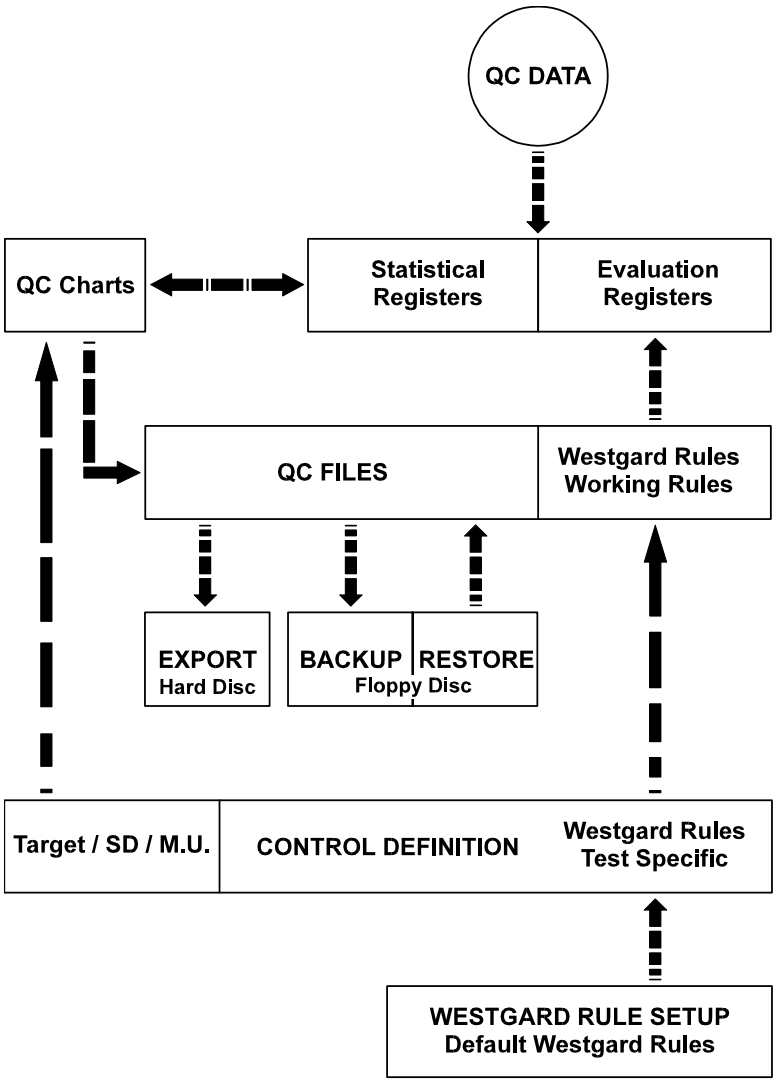
```
Delete Control file
Do you want to delete? NO
```

To confirm the deletion, press **<y><Enter>**. The file is removed from the QC File Directory. To deny the deletion, press **<Enter>**.

If an active file (blue) is selected for deletion, the error message “FILE IN USE! Cannot be deleted” will be displayed. Press **<any key>** to clear the message.

20.2.7 Flowchart of Information Transfer

The QC File contains all the information transferred from the Control Definition for each test when the QC File for that test was first activated. With the exception of modifications made to the Westgard rules, the file will always operate under the information transferred from the Control Definition at the time of file origination. The QC File Definition is used to set the working Westgard rules for each test if for any reason a change in rule evaluation is desired.



The evaluation criteria information stored in the QC File for each test is transferred to the evaluation registers. Note that there is no backward flow of Westgard rule setup from the QC File to either the Control Definition or the Westgard Rule Setup. Changes made to the Westgard rules in QC File will not be reflected in either the Control Definition or the default setup.

The QC File for each test stores data processed through the QC Chart for each test. This data may be backed up, restored or exported to an external quality control program.

20.3 QC Charts

Password security system = full access with restricted editing
PIN level accesses = 2 (full), 1 (full access with restricted editing) and 0 (limited access and prohibited editing).

The QC Charts menu provides access to the control charts that are automatically prepared for every active QC File. Each chart may contain up to 1000 run-generated data points.

Displaying QC data graphically is the easiest way to manually assess control performance. The Levey-Jennings chart has been the traditional type of control chart used by laboratories. Lines for the mean, 1SD and 2 SD values are drawn on the chart. The lines are labeled with the corresponding measured value. QC results are plotted and evaluated according to laboratory established acceptance/rejection criteria. With the advent of multirule evaluation, the chart design has changed slightly. Although the chart looks very much like a Levey-Jennings chart, the lines no longer represent the actual measured value. Since the multirules are based on SD deviation, on a multirule control chart the lines represent the mean and the deviations in SD from the mean or target value. The AMAX 200*AMAX* QC charts are multirule charts.

Prior to performing QC testing, the following prerequisites must be in place:

- Reagents have been defined;
- Tests have been defined;
- Controls have been defined;
- QC File has been created;
- Reagents have been assigned to a Reagent Layout; and
- Tests have been placed into a Test Group.

19.4
19.2
20.1.2
20.2.1
19.3
19.1

Prior to working with Q.C. charts, QC testing must be performed.

QC samples are entered using the ID Code defined in Control Definition as a preface to a 2-digit identifier sequence code. Up to 1000 QC results may be stored for any ID Code. The 2-digit sequence identifier may be any combination of the following:

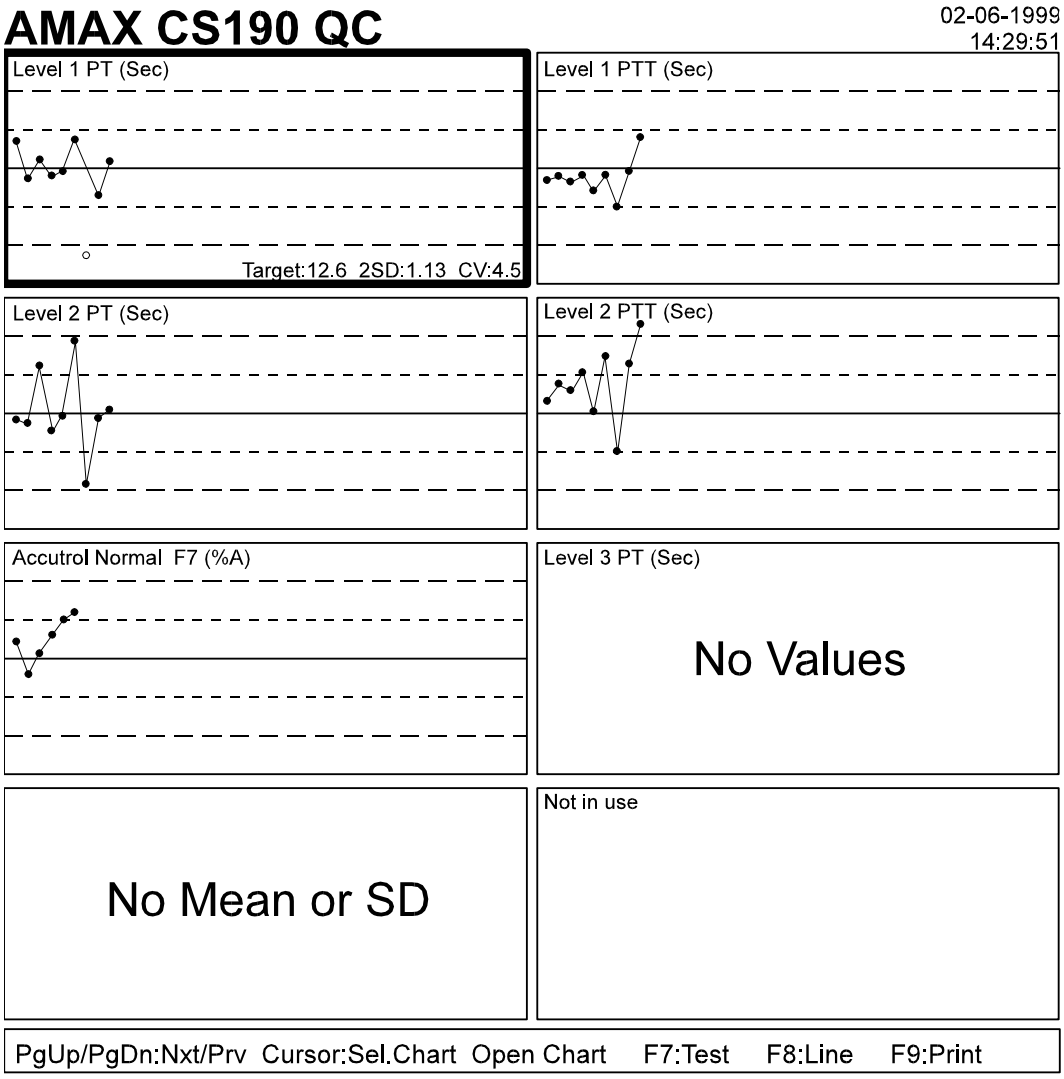
- 00 (zero zero) through 99
- AA through ZZ
- 0A (zero A) through 9Z
- A0 (A zero) through Z9

An ID Code + sequence identifier combination may only be used once in any given file format period. If the same combination is entered more than once, an audible alert and the message “multiple!!!” will be displayed.

Q.C. Charts may be accessed from the Main Menu or from within QuickStart. To open the multirule control charts from the Main Menu, press **<Q.C.><Q.C. Charts><Enter>**. To open the charts from within QuickStart, press **<Stat><Quick-Start><selected Test Group><F1><Q.C. Charts><Enter>**. The thumbnail (miniaturized) charts are displayed.

20.3.1 Thumbnail Charts

Password security system = full access
PIN level accesses = 2 (full), 1 (full) and 0 (full).



Note that instructions for the use of the window are displayed at the bottom of the display. The use of the various keys will be described in the following text.

Eight multirule charts are displayed on every page. If more than eight test QC Files have been opened, the next set of eight charts is accessed with the **<Page Down>** key. Use the **<Page Down>** key to negotiate through the pages of charts. The **<Page Up**> key will return the view to page 1. When on the last page of charts, pressing **<Page Down>** or **<Page Up>** will return the view to page 1.

Charts may be displayed in two orders. They may be displayed in Test order or Control order. When displaying in Test order, the charts are arranged by Test Code (according to the position in Test list) and then by the control name (according to the position in the Control Definition Control list). All charts for each test are displayed consecutively. When displayed in Control Order, the charts are arranged by Control Name (Control list order) and then by the test (Test List order). All charts associated with each control are displayed consecutively. The **Function Key <F7>** is a toggle between Test and Control display. It will either say “F7:Test” or

"F7:Control". Whatever option is being displayed is the option that is available, e.g. when the help area at the screen bottom indicates F7:Test, the order is currently set for display in control order. Press **<F7>** to toggle back and forth between display order options.

If a QC File has been opened on a test but no QC testing has been done on that test, the chart will say "**No Values**".

If a QC File has been opened on a test and QC testing has been done on that test, the data points will be plotted on the multirule chart. All horizontal lines are derived from the 2SD value of the selected target. The solid line in the middle is the target (± 0 SD); the two short dashed lines represent ± 1 SD; the two long dashed lines represent ± 2 SD; and the top and bottom boundaries of the chart represent ± 3 SD. The data points may be represented by either dots or lines. The **Function Key <F8>** is a toggle between dot and line display. It will either say "F8:Dot" or "F8:Line". Whatever option is being displayed is the option that is available, e.g. when the help area at the screen bottom indicates F8:Line, the order is currently set for dot display. Press **<F7>** to toggle back and forth between point display options.

If there are less than eight open files on a page of charts, the empty position(s) will have "**Not in Use**" in the upper left corner.

If the Target and/or 2SD value have been deleted on an open file, the chart for that test will say "**No Mean or SD**". Locate the associated Control Definition (blue assigned values) and reenter the missing value(s).

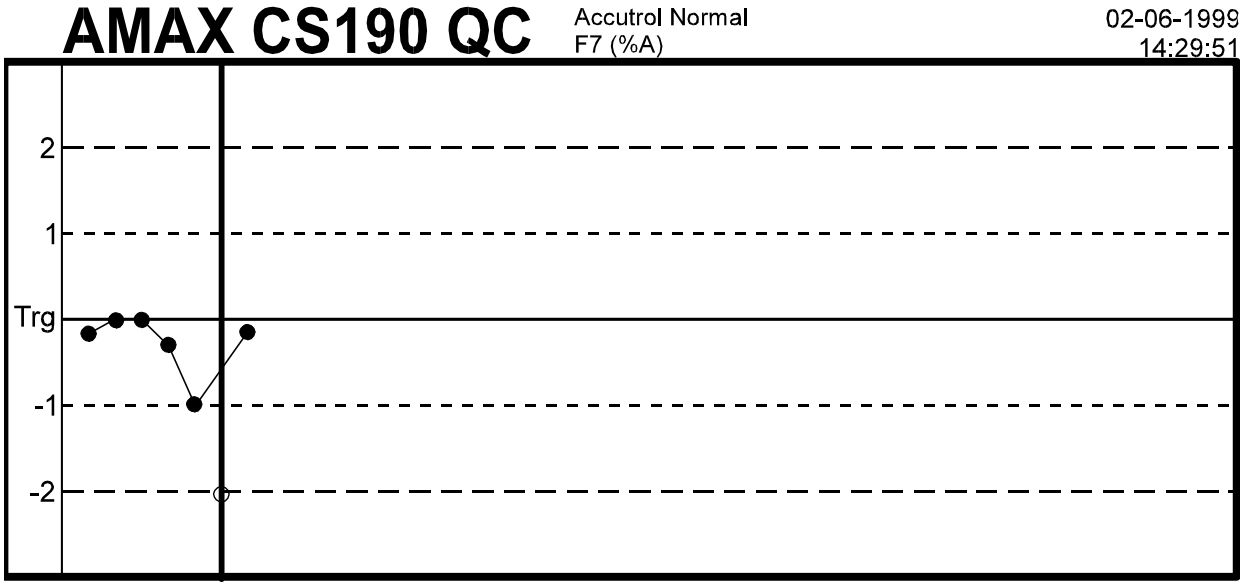
20.1.2.2

A page of thumbnail charts may be printed by pressing **<F9>** or **<Print Scrn>**. Each page must be printed separately.

The chart with the heavy outline is the position of the cursor. Negotiate through the charts using the **<arrow keys>**. If a chart contains more than two points, it may be opened to a full screen display (zoom chart) by moving to the selected test with an **<arrow key>** and pressing **<Enter>**.

20.3.2 Zoom Chart

Password security system = full access
PIN level accesses = 2 (full), 1 (full) and 0 (restricted areas).



Value	Measured on	By	Omitted on	By	Comment
49.31	02-06-99 09:16				Recalibrated
39.94	02-06-99 08:46		02:06:99 8:56	LCT0	VS:4-1s,VS:1-2s
44.98	02-05-99 11:24				
47.77	02-02-99 14:21				
49.75	01-29-99 09:53				
49.75	01-26-99 16:05				
48.75	01-15-99 13:01				

Chart	Width:		50
	Display:		5
Values	Total:		7
	Omitted:		1
	Days:		6
Target	Mean	2SD	CV
Lst 30	48.3	3.65	3.7
All	48.3	3.65	3.7
Cursor			
Man	50	10	

Cursor Value: 39.94
Measured: 02-06-99 08:46:16
Omitted: 02-06-99 08:56:28
By: LCT0
Note: VS:4-1s,,VS:1-2s

O:Omit Value F:QC File List R:Recalculate H:Cmd List F9:Print Report <Esc>Quit

20.3.2.1 Introduction

The zoom chart is a magnified version of the selected thumbnail chart. It allows close examination of QC results by providing detailed information about each point on the chart. It also provides access to editing functions.

The Control Name, Test Code and M.U. for the selected chart are at the top center of the screen.

The current date and time are displayed at top right.

There are three boxed areas in the display. The upper area of the display is the multirule chart. The box on the bottom left is the QC results listing. The green box indicates the position of the cursor in the listing. The box at bottom right is the statistical information area. The active area is indicated by a heavy outline.

The horizontal lines on the multirule chart are labeled to indicate the deviation away from 0 SD (Trg).

The data points will be displayed using the point option (dot or line) selected for the thumbnail charts. If in dot display, each accepted data point is represented by a solid blue dot connected to the next accepted point by a line. A valid (accepted) out-of-control point is solid red with a red connecting line from the previous point. The color of the line to the next point depends on whether or not the next point is in-control. An omitted (rejected) point is represented by an open red circle with no connecting line to the next or the previous point. If in line display, there are no data point dots for accepted points. The line goes from valid point to valid point. The line will be red immediately before an accepted out-of-control point. Omitted points will be open red circles.

The position of the cursor over one of the points is indicated by the vertical green line. The active area of the display is bounded by a heavy blue box.

20.3.2.2 Commands, Working with the Zoom Chart

There are a number of commands that are used when working with the zoom charts. Some of the more commonly used commands are displayed at the bottom of the screen. The onboard Command List may be accessed by pressing **<h>**. It is displayed in the results listing box. The commands are discussed below in an order different from the Command List display.

Chart display commands. There are five commands that are used to control the chart appearance.

Display Commands		
Command List	**Operator Entry**	**Description of function**
– (Minus):	**<–>** (either numerical or alphanumeric keyboard) Access Levels: 2, 1 and 0	Zoom out. Increases the width of the display. Brings more points into view. Chart may be changed to display from 30 to 1000 points. Chart width size is shown in the upper part of the statistical information box. The number of points in the display is shown directly below the chart width. The number will increase by 10 each time the "–" is pressed. If in dot display, the dots will change to little crosses at a width of 160. Holding the <–> down will rapidly change the chart width. Maximum width is 1000. The zoom size will keep from one session to the next session.
+ (Plus):	**<+>** (numeric keyboard) or **<Shift>** + **<+>** (alphanumeric keyboard) Access Levels: 2, 1 and 0	Zoom in. Decreases the width of the display. Brings fewer points into view. Chart may be changed to display from 30 to 1000 points. Chart width size is shown in the upper part of the statistical information box. The number of points in the display is shown directly below the chart width. The

Display Commands		
Command List	**Operator Entry**	**Description of function**
		number will decrease by 10 each time the "+" is pressed. If in dot display, the dots will change from little crosses to dots at a width of 150. Holding the <+ key> down will rapidly change the chart width. Minimum width is 30. Zoom size will keep from one session to the next session.
D:	**<d>** Access Levels: 2, 1 and 0	Display date in chart. At chart widths of 70 or less, the date the first data point of a day was run may be inserted into the chart. Pressing <d> a second time will remove the date. The date insertion is not kept from one session to the next.
I	**<i>** Access Levels: 2, 1 and 0	Brings up the QC File Description that includes the control and reagent lot number information. Press <Esc> to close the description window.
Shift+Cur. Lt:	**<Shift>**+**<←>** Access Levels: 2, 1 and 0	Shifts the chart to the right by 10 values bringing more points to the left into view and removing the 10 rightmost points from view. The chart position is not kept from one session to the next. The chart will always come up with as many of the most recent points that will fit on the chart (dependent on chart width setting).
Shift+Cur. Rt::	**<Shift>**+**<→>** Access Levels: 2, 1 and 0	Shifts the chart to the left by 10 values bringing more points to the right into view and removing the 10 leftmost points from view. The chart will always come up with as many of the most recent points that will fit on the chart (dependent on chart width setting).

Cursor commands. There are four commands that are used to control the position of the cursor in the chart.

Cursor Commands		
Command List	**Operator Entry**	**Description of function**
Cursor Lt/Rt:	**<←>** or **<→>** Access Levels: 2, 1 and 0	<←> Moves the cursor one point to the left. <→> Moves the cursor one point to the right.
Cursor Up/Dn:	**<↑>** or **<↓>** Access Levels: 2, 1 and 0	<↑> Moves the heavy outline (indicates active area) to the listing of results below the chart with a green box around the values associated with the cursor position

		on the multirule chart.. Continued pressing of the<↑> moves the cursor up the result listing and to the right on the chart. In similar manner, the<↓> moves the cursor down in the result listing and left in the chart.
Ctrl+Cur. Lt:	**<Ctrl>** + **<←>** Access Levels: 2, 1 and 0	Moves the cursor to the far left position in chart.
Ctrl+Cur. Rt:	**<Ctrl>** + **<→>** Access Levels: 2, 1 and 0	Moves the cursor to the far right position in chart.

There are a number of commands that are used in evaluating and editing of the data. Since these commands control important functions, they will be discussed in more detail after the table listing.

Evaluation and Editing Commands		
Command List	**Operator Entry**	**Description of function**
M:	**<m>** Access Levels: 2, 1 and 0	With > 3 points in chart, draws the mean deviation line.
C:	**<c>** Access Levels: 2, 1 and 0	Allows insertion of comment on a data point into the QC result list.
O:	**<o>** Access Levels: 2, 1and 0 Access Level: 2 only; Password prohibited	Allows a point to be omitted. Requires initial entry and a comment. Allows a Level 2 Operator to restore a point omitted by a Level 1 Operator.
F:	**<f>** Access Levels: 2 and 1	Opens a listing of all tests in the QC File Directory. The tests displayed in red are open active files whereas the tests in blue are associated with inactive files.
Page Down:	**<Page Down>** Access Levels: 2 and 1	Moves the cursor down a page in the file listing.
Page Up:	**<Page Up>** Access Levels: 2 and 1	Moves the cursor up a page in the file listing.
A:	**<f><select file><a>** Access Levels: 2 and 1	Does not appear in command list. Appears at bottom of screen after a file is selected from the file listing. After is file is selected from the file listing, it may be appended to the current zoom chart.
R:	**<r>** Access Levels: 2 and 1	Recalculates the mean values. Used after appending data from one file to another.
T:	**<t>** Access Levels: 2, 1 and 0	When > 30 points present, the target may be changed from manual (transferred from control definition file) to the mean of the last 30 results, the total mean or a cursor mean (floating mean).
Z:	**<z>** Access Levels: 2, 1 and 0	Displays the Z distribution score.

Evaluation and Editing Commands		
Command List	**Operator Entry**	**Description of function**
S:		Not functional. Where saving is required, you will automatically be asked if you want to save any changes you have made.

20.3.2.3 **Mean30/Mean** function utilizes a trend analysis technique to calculate an exponentially smoothed estimate of the mean of the last 30 data points each time a new control observation is added to the data. The most recent observation is weighted most heavily in the calculation and older observations gradually fade in importance as their age increases. A trend analysis is primarily sensitive to systematic error or inaccuracy whereas a multirule or Levey-Jennings plot is sensitive to random error or imprecision. To display the trend line, press **<m>**. The trend line displays as a magenta line.

20.3.2.4 **Comment** on a data point. All QC results are listed in the lower left box. The most recent result is at the top of the list. The oldest result is at the bottom of the list. The vertical green line in the multirule chart indicates the position of the cursor. The horizontal green box in the result listing surrounds the data associated with the data point at the vertical green cursor on the multirule chart. Each result is listed along with the date and time the result was processed and, if the security system has been invoked, the operator signed on during processing. Violations of enabled Westgard rules are automatically inserted into the Comment column as the incoming QC data is processed. Comments may be made on any data point. How the comment is inserted depends on whether or not the point in question has an automatically inserted violation comment.

To insert a comment on a point with no violations, position the vertical cursor over the point to be commented on and press **<c>**. The selected box will now be the statistical information box. “Note” will be in red with the cursor positioned below it in the white box. Type **<appropriate comment>** (character limit = 28) **<Enter>** or **<Esc>**. The comment will be copied to the Comment column in the QC Result List. When the zoom chart is exited, “Save updatings? NO” will be displayed at the bottom of the screen. To confirm and save the comment, backspace to remove “NO” and press **<y><Enter>**. To deny the comment, press **<Enter>** or **<n><Enter>**.

Comments made on any data point without an automatic rule violation may be commented on multiple times. The commenting procedure is slightly different for points that have automatically inserted rule violations and for omitted points.

Before a comment may be made on a data point with a rule violation, the point must be first omitted (at least temporarily). If making a comment either in addition to or in place of the automatic violation comment is desired, press **<o><appropriate initials> <appropriate comment><Enter>**. If the point is to be omitted, the omission and comment will become permanent when the zoom charted is exited and saved. If the point is not to be omitted, press **<o>** again. When the zoom chart is exited and saved, the new comment will be saved.

20.3.2.5 Omit a data point. Data points collected from all runs that are rejected should be omitted (even if some of these values are within 2SD of the mean).[1]

A Level 1 or 2 Operator may omit any unedited point. A Level 2 Operator may restore a point previously omitted by a Level 1 Operator. A Level 4 Service-level Operator may restore points omitted by both Level 1 and 2 Operators. No point restoration is allowed with the Password security system.

a. **To omit a point**, position the vertical cursor over the point and press **<o>**. The selected box will now be the statistical information box. If the PIN security system is not enabled, the cursor will be in the initial area. An initial (up to 4 characters) is required for all data point omissions. Type **<Initials><Enter>**. If the PIN security system is enabled, the signed-on user code is automatically inserted into the comment area. The cursor goes to the "Note:" area. Enter comments as appropriate. As soon as **<Enter>** or **<Esc>** is pressed, the date and time the omission was done along with the initials of the editor are copied to the to the Comment column in the QC Result List. The omitted point will display as an open red circle on the multirule chart. No lines connect it to the previous or next point.

   Until the zoom screen is exited, the omission is not irrevocable. To cancel the omission, press **<o>** again. In this way the effect of point omission may be judged prior to making the omission permanent.

   Before a comment may be made on a data point with a rule violation, the point must be first omitted (at least temporarily). If making a comment either in addition to or in place of the automatic violation comment is desired, press **<o><appropriate initials> <appropriate comment><Enter>**. If the point is to be omitted, the omission and comment will be saved when the zoom charted is exited and saved. If the point is not to be omitted, press **<o>** again. When the zoom chart is exited and saved, the new comment will be saved.

   Once the zoom chart is exited and the updating has been saved, the omitted point can not be commented or restored by a Level 1 Operator. A Level 2 Operator may restore and comment on a point omitted by a Level 1 Operator. Omission of a point by a Level 4 Operator cannot be reversed.

   When a point has been omitted, all counters (VS, VT and VC) associated with the point are reset to 0.

   Omitted data points are excluded from subsequent statistical analyses and are not transferred to the export file.

b. To restore a previously omitted point:

   Password security system: prohibited
   PIN security system: Levels 2 and 4 only; Levels 1 and 0 prohibited.

   Once a point has been omitted, it may only be restored by a higher security level Operator. A Level 2 Operator may restore points omitted by a Level 1 Operator. A Level 4 Operator may restore points omitted by Level 1 and 2 Operators. A point omitted by a Level 4 Operator cannot be restored.

   (1) Move the cursor to the point to be restored. Press **<o>**. The level listed in the "Level:" column must be less than that of the signed on Operator,

e.g., if the level of the signed-on operator is 2, the level listed for the Operator who omitted the point must be 1.

(2) The cursor will be in the "Note:" position. Any comment made at this point will not be recorded. Press **<Enter>** followed by **<o>**. The point will now be blue and have lines running from the last preceding valid point and to the next valid point. **Do not escape the screen yet.**

Before exiting the zoom chart, the comment process must at least be attempted. Although not necessary to actually make a comment, the "Note:" area must be accessed prior to exiting the zoom chart. If the "Note:" area is not accessed at least once during the restore process, the restoration process will not be saved.

Press **<c>**. The cursor will again be in the "Note:" entry field. Any entry made at this point will be recorded. If making a comment is desired, type **<appropriate comment><Enter>**. If no comment needs to be made, press **<Enter>**. When the zoom chart is exited and the update is saved, the point(s) is restored. If restoring multiple points, the comment field needs to be entered on only one point in order to prompt the "Save updatings? NO" screen to be displayed on exit from the zoom chart.

(3) Press **<Esc>**. "Save updatings? NO" is displayed at the bottom of the screen. <**Backspace to remove NO>** and type **<y><Enter>**. The previously omitted point is restored.

20.3.2.6 **Append** a file. Data from one file may be transferred to and combined with the data from another file.

a. To append a file, with the zoom chart open for the test the data is to be appended to, press **<f>** to open the QC File List.

b. A listing of all the files in the QC File Directory is displayed. Files in red are active files. Files in blue are inactive. Both active and inactive files may be appended. The **<Arrow>**, **<Page Down>** and **<Page Up>** keys are used to move through the list.

Move the cursor down to the file to be appended, and press **<Enter>**. Two action options are displayed at the bottom of the screen. "N:New File" and "A:Append to existing".

c. Press **<a>** and the data points from the selected file are copied to the existing file. The multirule chart will now temporarily contain both sets of data. "Multiple files" is displayed opposite the Control Name at the top of the chart. As long as "multiple files" is displayed the file append is not permanent. The data may be manipulated and edited in a variety of ways.

d. The targets, means, 2SDs and CVs may be recalculated to include the newly appended data by pressing **<r>**. Any other editing functions that may be done on a file may also be performed on an unsaved appended file (except F9:Print report). Until the zoom chart is exited and the update saved, the data append and any data manipulation is temporary.

e. When data manipulation is completed, if the files merger is to be permanent, press **<Esc>** to exit the zoom chart. The query "Save updatings? NO" will be displayed.

To confirm the file merger, backspace to remove "NO" and press **<y><Enter>**. The two files will be permanently merged. To return the chart to the original unappended state, when "Save updatings? NO" is displayed, press **<Enter>**.

20.3.2.7 To change the **target** value. When a chart is first created, the limits are calculated using the 2SD entry in the Control Definition. The target in a newly created chart is the manually entered target value in the Control Definition. As soon as enough points have been collected to be statistically valid, the target source may be changed. Data from 30 points is considered statistically valid. There are three types of targets.

- **Manual**. A fixed central value that does not vary with data input. The fixed target is the target value defined in the Control Definition. A fixed target functions with fixed limits. The fixed limits are based on the 2SD value in the Control Definition. A change in the Control Definition for either of these values will be reflected in the multirule chart. The fixed target and 2SD is always displayed in the statistical information box as "Man". When "Man" is selected as the target, the fixed mean and 2SD values are used to construct the chart limits. The fixed mean is the base value used for all evaluations. The fixed 2SD value is used for all SD-based rule evaluations.
- **All**. A floating central value that varies with every data input. Historical data has as much influence as recent data. The limits are unfixed and vary according to the 2SD value. When "All" is selected as the target, the mean and 2SD values collected from all data in the file are used to construct the chart limits and to evaluate the incoming data.
- **Last 30**. A floating mean and 2SD derived from the last 30 measurements in the file. The mean and 2SD for the last 30 measurements are used for chart construction and evaluation. Historical data (older than 30 points) has no influence. The Last 30 mean and 2SD values reflect recent performance. A related setting is "**Cursor**". When cursor is selected as the target, the Mean and 2SD values displayed are the cumulative last 30 mean and 2SD of all the points up to and including the selected data point. The chart limits are reconstructed every time the cursor moves to a new data point. The mean and 2SD of the last point will be the same as the "Lst30" mean and 2SD. A cursor target is not generally used for active data collection. It sometimes is useful when troubleshooting.

To change the target, press **<t>**. The statistical box will be highlighted. Use the **<↑>** and **<↓>** to select the desired target. Press **<Enter>**, **<Esc>** or **<Right or Left Arrow>** to complete the selection.

If working with an unsaved appended file, the data must be recalculated (<r>) before the cursor mean and SD can be displayed.

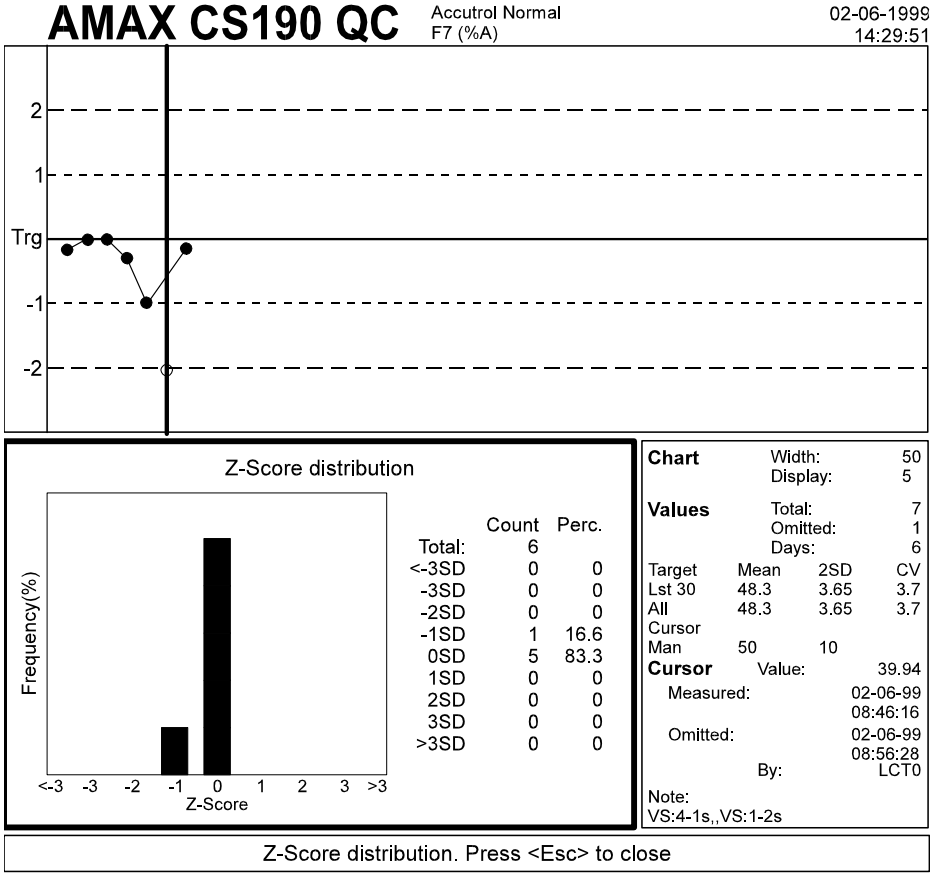
20.3.2.8 The "**New file**" command may be used to negotiate through the zoom charts without first going back to the thumbnail charts. It is also used to view inactive files in the QC File Directory. It is the only way to examine charts for tests that have been deleted from the test programming.

Press **<f>** to open the QC Directory file listing. Active tests are red and inactive tests are blue. Move the cursor to the test whose zoom chart you want to see. Press **<Enter><n>**. The zoom chart for the selected test will be displayed.

20.3.3 Z-Score Distribution Chart

A z-score is a calculated value that shows how many standard deviations a control result is away from the target value. It is the difference between the result and the target divided by the SD for the target. The calculated z-score may be plotted on a chart. A "multirule chart" is a z-score chart. Z-scores may also be plotted as a bar graph. The most common use of z-score bar graphs is to plot the results of multiple controls on the same chart. This greatly facilitates the manual evaluation of across-material results.

Z-scores may also be used to plot a distribution histogram on which SD is the horizontal axis and the frequency of occurrence of each deviation is the vertical axis. The z-score distribution histogram shows the frequency of occurrence of the z-scores. A test whose performance is stable should reflect "normal" or gaussian distribution.



To display the z-score distribution chart, with the zoom chart open, press **<z>**. The z-score distribution graph is displayed in the lower left box.

The total number of points and the number of points occurring at each major SD level are listed in the "Count" column. The frequency percentage of the points at each SD level is listed in the "Perc." Column.

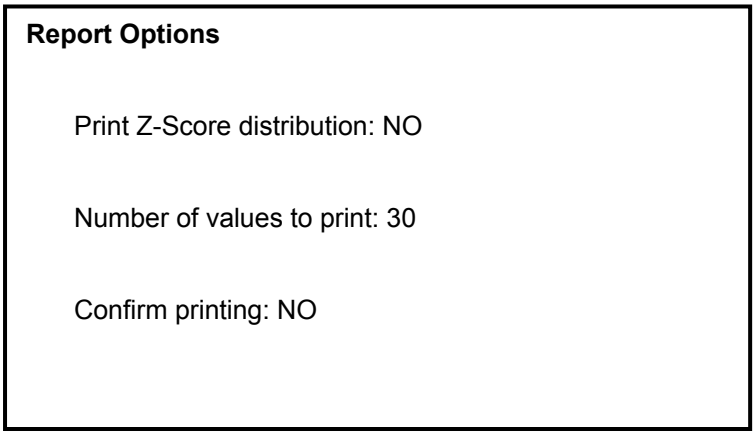
20.3.4 Print QC Report

QC reports may be printed in several different ways. The Thumbnail charts may be printed by pressing **<F9>**. Each page of charts must be printed separately.

More detailed QC reports may be printed from within the zoom chart screen. Move the cursor to the thumbnail chart of the **desired test** and press **<Enter>** to open the associated zoom chart.

A replica of the zoom chart may be printed by pressing **<Prnt Scrn>**. The printout will include the multirule chart as displayed, up to eighteen of the QC results and comments in the QC result box, and all of the information in the statistical information box. Note that only eighteen of the QC results may be listed using this technique.

A printout of the multirule chart and a specified number of QC results may be printed by pressing **<F9>**. A Report Options dialog box will open.



Respond to each question as appropriate. The time required for the printout is dependent on how much is included in the report request.

Note that these reports do not include all the information contained in the Statistical Information box. Only the selected target, 2SD and CV will be printed.

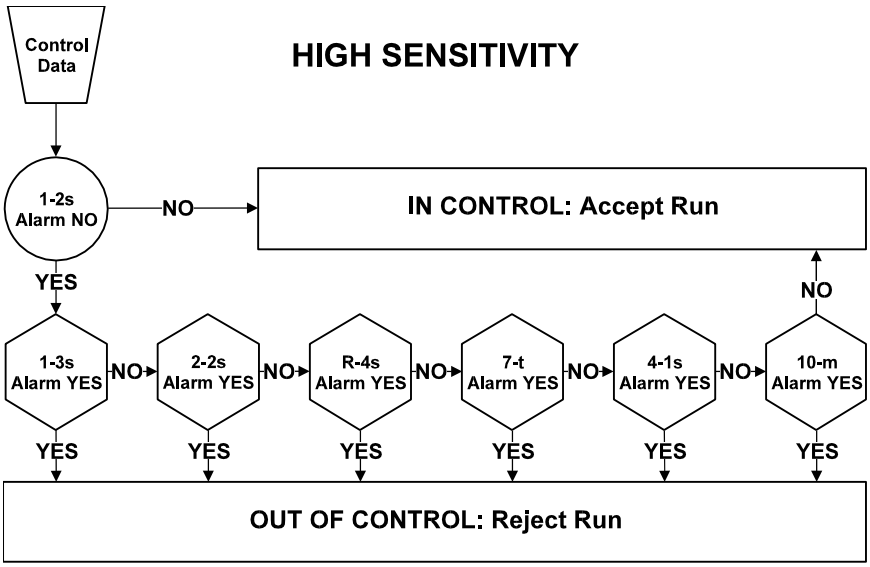
A temporarily appended file may not be printed using <F9>. The message “Cannot report multiple files! Use Print Screen to print chart” will be displayed. If a printout of a temporarily appended file is desired, press **<Prnt Scrn>**.

20.3.2.6

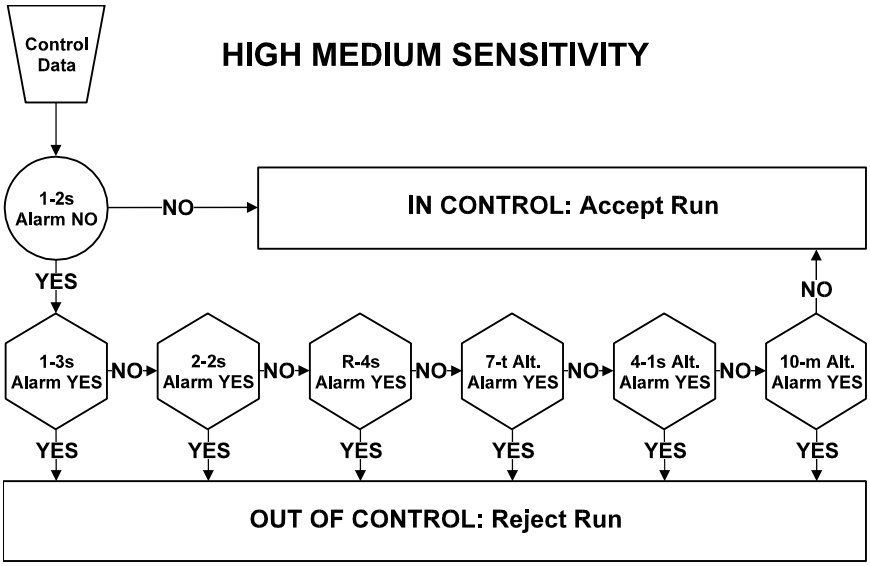
20.4 Rule Sensitivity Settings

The sensitivity of error detection should be set to fit the performance characteristics of every test. Some tests are characterized by very stable performance. Other tests are not. Rules should be selected so that error detection is as high as possible and the false rejection rate less than 5%.

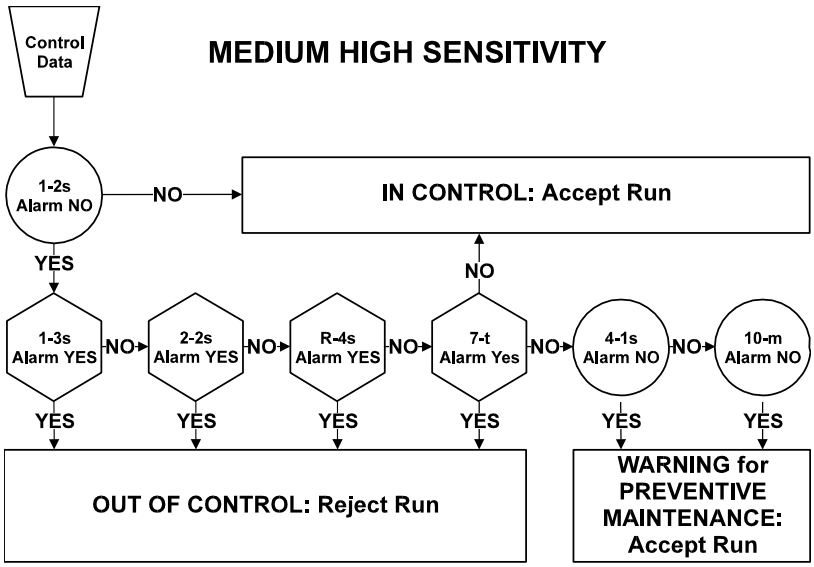
The error detection sensitivity is high when all rules are enabled and the alarm is set to ON for all rules except 1-2s.



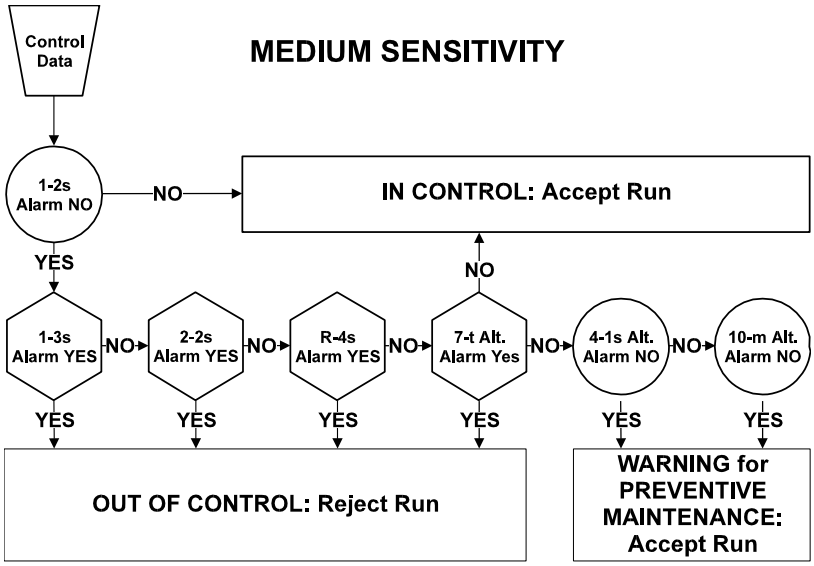
The 4-1s and 10-m rules are sensitive to small systematic errors that are not always significant enough to reject a run. The benefit of high sensitivity is offset by the increase in false rejection. Changing the 4-1s and 10-m to the “Alternate” option increases the difficulty in violating the rules thereby decreasing the sensitivity somewhat.



The 4-1s and 10-m rules could be eliminated in an attempt to reduce the false rejection rate. An alternative is to use these rules as warning rules to trigger inspection of the procedure or to invoke maintenance procedures. Changing the alarm status will further reduce the sensitivity. Although the alarm will not sound, the violations will be recorded in the QC result listing.

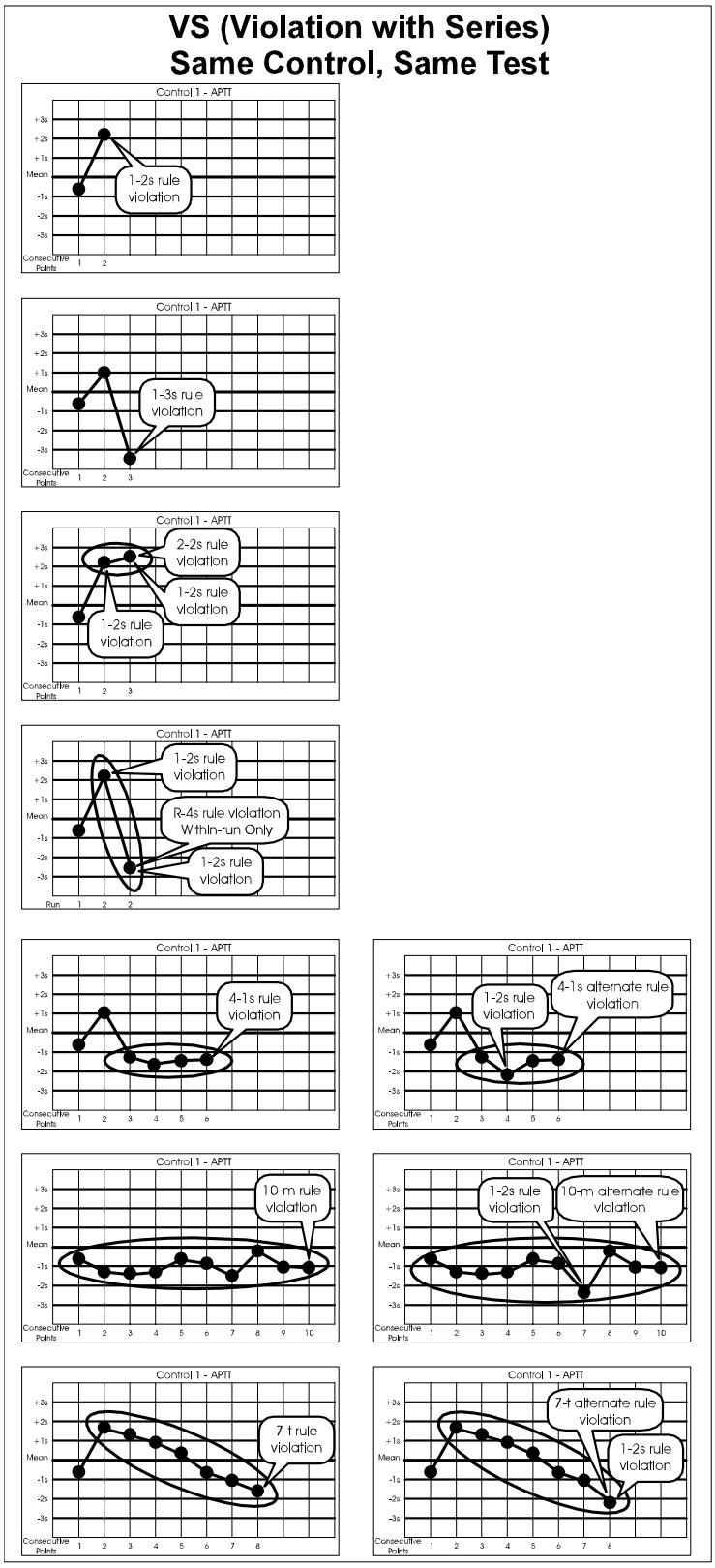


Substituting the “Alternate” options for the 4-1s and 10-m will increase the difficulty in violating the rules thereby decreasing the sensitivity.

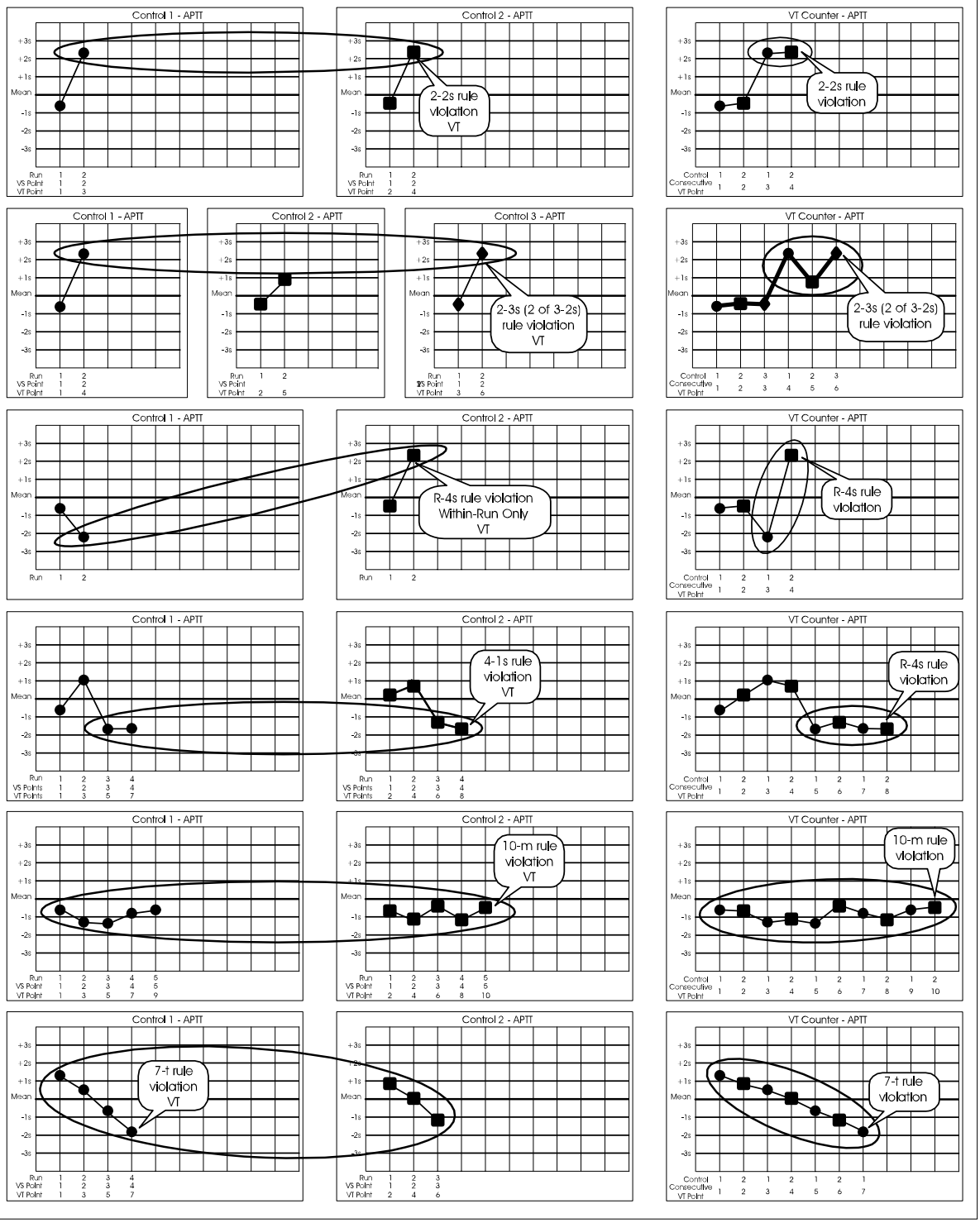


Adjust the sensitivity as appropriate for each test procedure. There is no one setting that will be the best for every test.

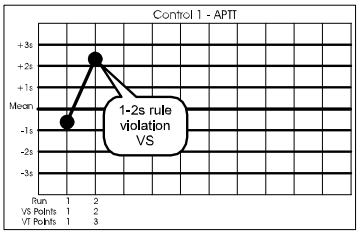
20.5 Violation Examples

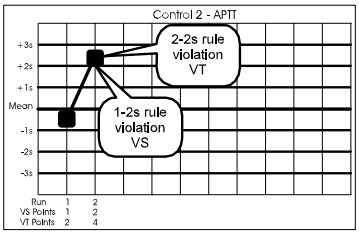


VT (Violation within Test)
Different Control, Same Test

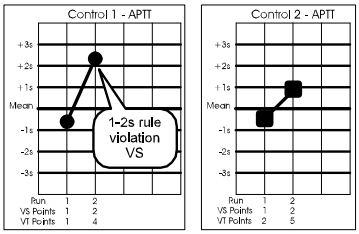

Control 1 - APTT
Control 2 - APTT
VT Counter - APTT
2-2s rule violation VT
2-2s rule violation
Control 1 - APTT
Control 2 - APTT
Control 3 - APTT
VT Counter - APTT
2-3s (2 of 3-2s) rule violation VT
2-3s (2 of 3-2s) rule violation
Control 1 - APTT
Control 2 - APTT
VT Counter - APTT
R-4s rule violation Within-Run Only VT
R-4s rule violation
Control 1 - APTT
Control 2 - APTT
VT Counter - APTT
4-1s rule violation VT
R-4s rule violation
Control 1 - APTT
Control 2 - APTT
VT Counter - APTT
10-m rule violation VT
10-m rule violation
Control 1 - APTT
Control 2 - APTT
VT Counter - APTT
7-t rule violation VT
7-t rule violation

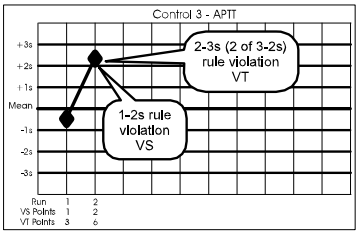
VS/VT (Violation within Series and within Test)
Same or Different Control, Same Test



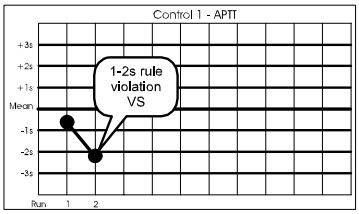


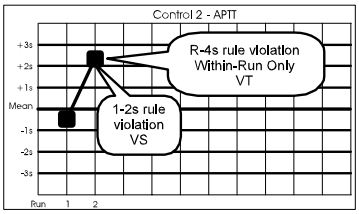
VS C1	VS C2	VT APTT
-0.7	-0.4	-0.7
2.2	**2.1**	-0.4
		2.2
		2.1





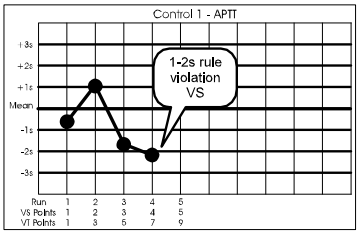
VS C1	VS C2	VS C3	VT APTT
-0.7	-0.4	-0.5	-0.7
2.2	0.8	**2.1**	-0.4
			-0.5
			2.2
			0.8
			2.1

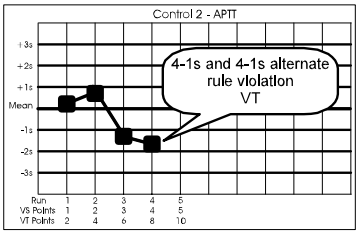




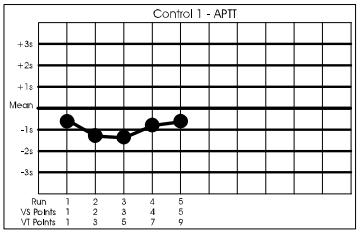
VS C1	VS C2	VT APTT
-0.7	-0.4	-0.7
-2.2	**2.1**	-0.4
		-2.2
		2.1

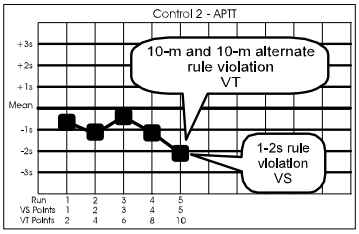
R-4s = abs (Previous Value - Current Value) >4



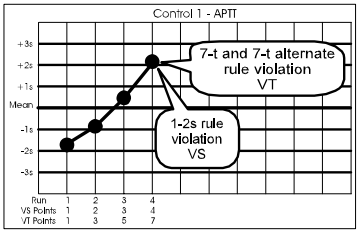


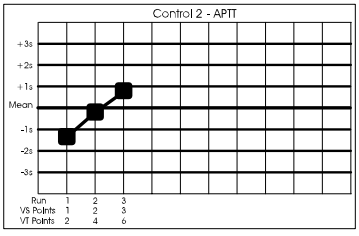
VS C1	VS C2	VT APTT
-0.7	0.3	-0.7
1.0	0.8	0.3
-1.8	-1.3	1.0
-2.1	-1.8	0.8
		-1.8
		-1.3
		-2.1
		-1.8





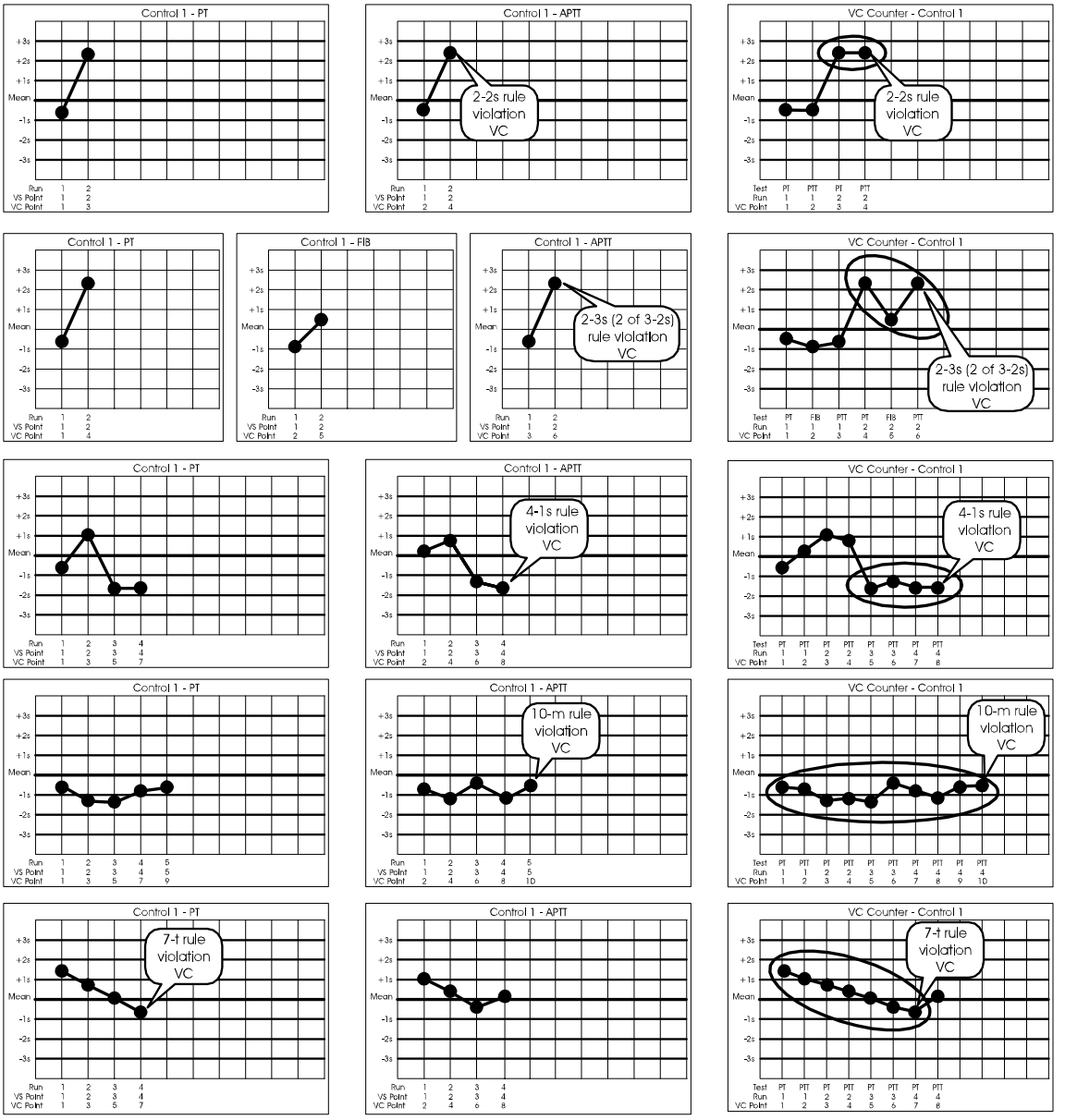
VS C1	VS C2	VT APTT
-0.7	-0.8	-0.7
-1.1	-1.0	-0.8
-1.2	-0.4	-1.1
-0.9	-1.1	-1.0
-0.8	**-2.1**	-1.2
		-0.4
		-0.9
		-1.1
		-0.8
		-2.1





VS C1	VS C2	VT APTT
-1.8	-1.4	-1.8
-1.1	-0.3	-1.4
0.4	0.8	-1.1
2.1		-0.3
		0.4
		0.8
		2.1

VC (Violation within Control)
Same Control, Different Test


Control 1 - PT
Control 1 - APTT
2-2s rule violation VC
VC Counter - Control 1
2-2s rule violation VC
Control 1 - PT
Control 1 - FIB
Control 1 - APTT
2-3s (2 of 3-2s) rule violation VC
VC Counter - Control 1
2-3s (2 of 3-2s) rule violation VC
Control 1 - PT
Control 1 - APTT
4-1s rule violation VC
VC Counter - Control 1
4-1s rule violation VC
Control 1 - PT
Control 1 - APTT
10-m rule violation VC
VC Counter - Control 1
10-m rule violation VC
Control 1 - PT
7-t rule violation VC
Control 1 - APTT
VC Counter - Control 1
7-t rule violation VC

20.6 Distribution

The "Statistics" section of each test definition defines how patient results will be stored and sorted for display of the distribution statistics. For distribution purposes, patient results may be stored as either the measured value (time or mE), a ratio to a known standard, or as a curve-calculated result. The range of results to be included in the distribution analysis is also defined. Only results within the defined range are stored in the distribution file. If "N" is selected as the type of result, no results will be stored.

19.2.5

20.6.1 Distribution Chart and Report

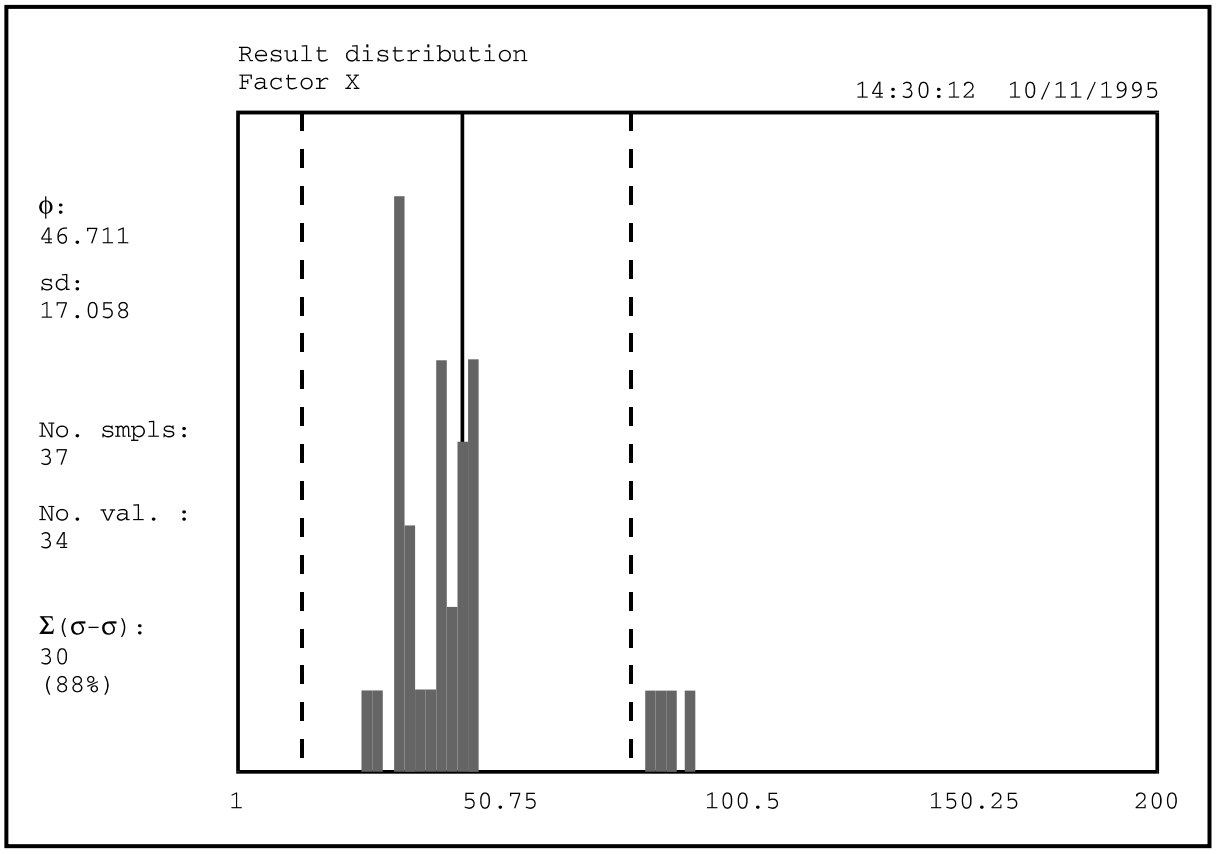
<QC><Distribution>. The "Distribution" dialog window appears.

[Distribution]

Select test :

Select the test by either entering the **Test Code, Test Number** or by pressing **<+><Enter>** to bring up the Test List. Move the cursor to the desired test and press **<Enter>**.

If there is data in the selected test distribution file, the distribution chart and report are displayed.



Statistics - Population Distribution Chart and Report	
Item	**Description**
Factor X	Test name
14:30:12 10/11/1995	Time and date printed
ϕ: 46.711	Population mean
sd: 17.058	Population standard deviation
No. smpls: 37	Total number of samples
No. val.: 34	Number of results within designated range
Σ(σ-σ): 30 (88%)	Number and percentage of results within 95% confidence limits (± 2 SD).

20.7 Calibration Curves

The "Calib. curves" option of the QC menu provides quick access to display current calibration curves.

<QC><Calib. curves>

The "Calib. curves" dialog window appears.

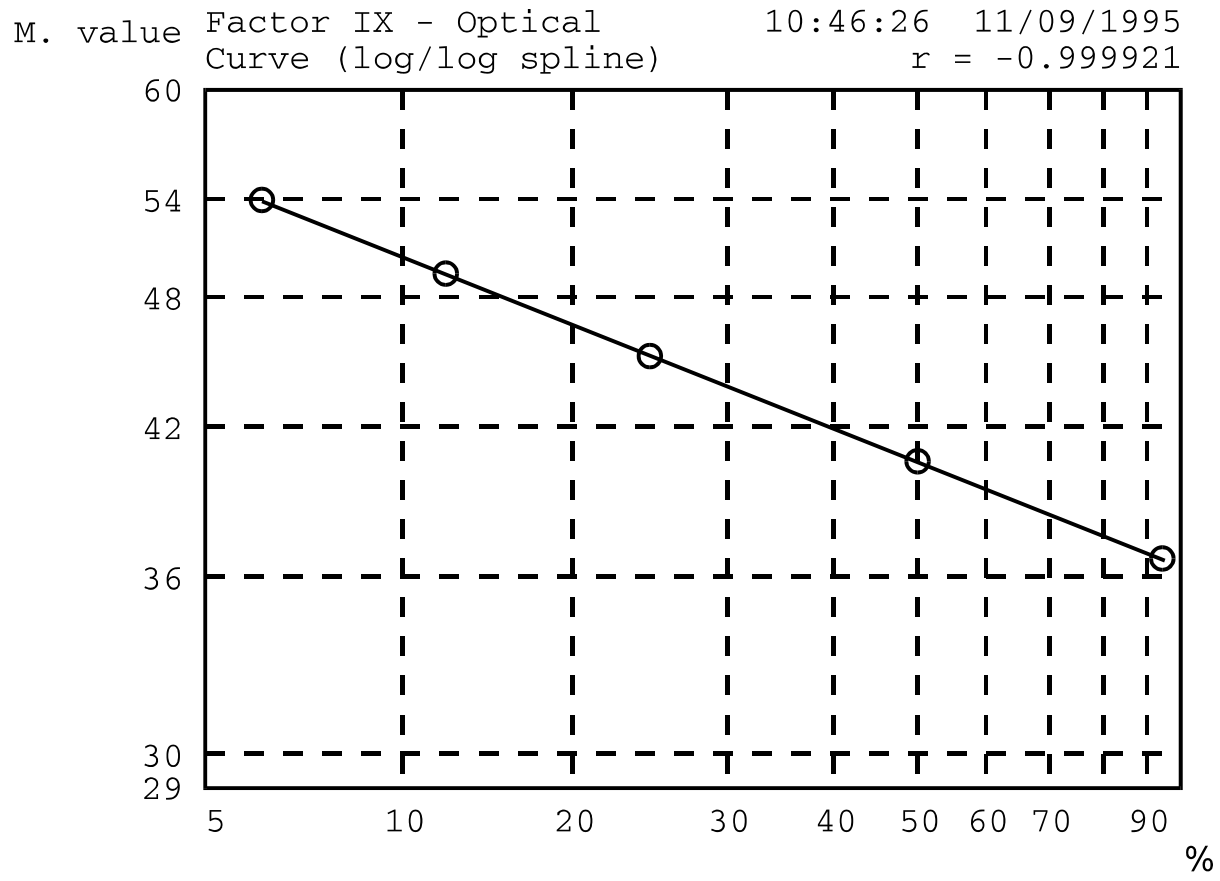
[Calib. Curve]

```
Select test :
```

Select the test by either entering the **Test Code**, **Test Number** or by pressing **<+><Enter>** to bring up the Test List. Move the cursor to the desired test and press **<Enter>**.

If there is a calibration curve for the selected test, the graph is displayed. Calibration is discussed in Section 22.

22



20.8 References

1. Westgard, JO, E Quam, and T. Barry. 1998. Basic QC Practices, Training in Statistical Quality Control for Healthcare Laboratories. WesTgard Quality Corporation, Madison, WI.
2. Westgard, JO, and PL Barry. 1986. Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes. AACC Press. Washington, DC.
3. Westgard JO, PL Barry and MR Hunt. 1981. A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry. Clin Chem 27(3):493-501.
4. Paulson, R and M Wachtel. 1995. Using Control Charts for Quality Assurance. Laboratory Medicine 26(6):400-407

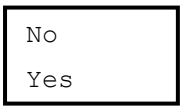
21 END MENU.....21-1
21.1 REMOVE STAT SAMPLES 21-1
21.2 HOST STATUS 21-1
21.3 PRINTER BUFFER 21-2
21.4 DOS SCREEN 21-2

Password security system = unrestricted
PIN security system = 2, 1 and 0

When testing is completed, the instrument either may be left on to be available for additional testing; or, may be powered down using the End procedure.

The “End” menu is used to exit the AMAX 200 operating program.

Press **<e>** or move the cursor to **“End”** and press **<Enter>**. The “End” menu is displayed.



There are only two options. Selecting **<No>** closes the menu with no action taken. Selecting **<Yes>** starts the exit procedure.

Before allowing exit, the AMAX 200 checks to verify that certain shutdown conditions are met.

- No Stat samples remain in Stat positions;
- Data is not being transmitted to a host computer; and,
- The printer buffer is empty.

If any of these conditions are not met, either a message will be displayed giving instructions (“Remove Stat Samples”); or, a dialog screen will be displayed (“Host Status” or “Printer Buffer”).

21.1 Remove Stat Samples

If Stats are programmed when <End><Yes> is selected, a screen requesting removal of Stats is displayed. Stats may be removed and assigned a tray position prior to initiating the exit procedure. If Stats are not transferred prior to exiting the program, they will be automatically removed and transferred to the patient archive. Samples with unprocessed tests will not be assigned to a tray for processing.

<Stat><#. position><F10>. Sample ID and result information is transferred to the patient archive files. Samples with unprocessed tests will be appended to the current tray for later processing.

21.2 Host Status

If the data link is active when <End><Yes> is selected, the “Host-Status” screen will be displayed. Exit will be disallowed until data transfer is completed.

The “Host-Status” may be checked at any time by pressing **<Alt-F3>**. If data transfer is active, wait until transfer is completed to exit the operating program.

The “Lis” status box in the right corner of the status bar always indicates the current host interface status.

Display	Color	Description
Lis	Black on white background	Last transmission (import or export) completed with no error.
Lis	Black on red background	Last transmission unsuccessful. Error during either data import or export.
Imp	Yellow on white background	Data being imported after previous successful import transmission.
Imp	Blinking yellow on red background	Data being imported after previous error in import transmission.
Exp	Yellow on white background	Data being exported after previous successful export transmission.
Exp	Blinking yellow on red background	Data being exported after previous error in export transmission.

21.3 Printer Buffer

If there is unprinted data in the printer buffer when <End><Yes> is selected, the "Printer Buffer" screen will be displayed. Exit will be disallowed until the printer buffer is empty.

The most common reasons that the buffer is not empty is that the printer is off, not on-line, or has run out of paper. Correct the adverse circumstance as necessary. Printing will start automatically.

The data in the buffer may be deleted if it is not needed. To delete the contents of the printer buffer, press **<Esc>** once, or **<Enter>** repeatedly until the last page of the contents is displayed followed by an additional **<Enter>**. The message **"Delete? NO"** will appear at the bottom of the screen. Press **<y><Enter>** to delete the buffer contents. To exit without emptying the buffer contents, press **<Enter>**. To print the contents, correct any condition disabling the printer. Buffer contents will be printed automatically as soon as the disabling condition is remedied.

The contents of the printer buffer may be checked prior to initiating the exit procedure. When the **<Alt>** key is pressed, a listing of the active function keys is displayed. "F8" is the printer buffer function key. The only time "F8" will be listed as an active function key is if there is unprinted data in the printer buffer. Press **<Alt-F8>** to display the contents.

21.4 DOS Screen

When all the exit conditions are met, the operating program is exited to the DOS screen displaying the currently active drive and path.

When at the DOS screen, the instrument may either be powered down or the operating program may be re-entered.

To power down, press the OFF/ON switch to the OFF position. The green light will go out. Switch peripheral equipment (PC, printer and monitor) off.

To re-enter the program from the DOS screen, type **<a><Enter>**. The operating program will be initiated. Upon re-entry, the Main Menu will again be displayed.

22 CALIBRATION 22-1
22.1 AUTOMATIC DILUTION 22-1
22.2 MANUAL DILUTION 22-5
22.3 SINGLE-POINT CALIBRATION 22-6
22.4 DERIVED FIBRINOGEN 22-6

Password security system = laboratory-defined password
PIN security system = 2 and 1 (full access), 0 (prohibited)

Calibration is the procedure used to prepare a standard curve against which measured values are compared and a result calculated. Standard curves are usually prepared using dilutions of known reference plasma. From 2 to 8 dilutions may be used to prepare a calibration curve.

With software version 3.1.13, once calibration is completed, the new curve will be used to calculate the results of all new samples added to the data archive and on repeated tests. The results on any unrepeated tests already in the archive will not be recalculated.

Dilutions may be prepared automatically or manually.

22.1 Automatic Dilution

The AMAX 200 can automatically prepare dilutions. All dilutions are prepared relative to the concentration of Standard 1. The instrument can prepare dilutions up to 1:80 as primary dilutions (395 µL buffer/5 µL Reference Plasma). Dilutions greater than 1:80 will be prepared using one of the already prepared dilutions. The Dilution Factor is calculated by dividing the concentration of each point by the concentration of point 1. The total volume for each dilution is always 400 µL. The volume of Reference Plasma required to prepare the dilutions is calculated by multiplying 400 by the calculated Dilution Factor. The volume of Reference Plasma required to carry out an automatic calibration will always depend on the number of points defined in the curve and the concentration ratio of each point to the Reference Plasma. Although all dilutions are prepared in concentration as relative to Standard 1, this does not mean that all dilutions will be prepared from Standard 1. Dilutions calculated as requiring less than 5 µL of Standard 1 per 400 µL will be prepared from an already prepared dilution. The dilution used will be the lowest dilution which will require $\geq$ 5 µL to prepare the dilution.

Curve Point	Reference Plasma Concentration (%)	Dilution Factor	Reference Plasma volume required (µL)
1	112	1	
2	100	0.893	357
3	80	0.714	286
4	60	0.536	214
5	40	0.357	143
6	25	0.223	89
7	10	0.089	36
8	1	.00892	3.6
Volume Reference Plasma Required for dilutions =			1125
Note that point 8 will not be prepared from the undiluted Reference Plasma. It will be prepared using 5 µL of Standard 3.			
Note that in addition to the calculated volume of Reference Plasma required, a sufficient volume of Reference Plasma must remain in tube #1 after dilution preparation for testing to be performed in duplicate.			

To perform a calibration:

1. Password security system: <System><Password><Parameters><Tests>

   PIN security system: **<Level 1 or 2 Sign-On><System><Parameters><Tests>**

   The Test List is displayed. Select the test to be calibrated. Move the cursor to the **appropriate test** and press **<Enter>**. The "Test Parameters" dialog window opens.

2. Move the cursor to the **Calibration section** and press **<Enter>**. The Calibration window opens.

[Calibration]

F1:Type F2:Calibrate F3:Curve F3:Graphic

Curve type	:2	Curve: Value	Sec/mE
Dilution r	:5	116	38.3
Max. value	:200	58	41.4
Standard	:0	29	45.8
ISI-Factor	:0	14.5	50.9
Max. CV	:10	7.25	57.8
Max time	:75	0	0
Max time 2	:0	0	0
Delay	:25	0	0
Impulse t.	:0	r:-0.9999721	

   The active function keys vary according to location within the window.

   A. **<F1:Type menu>** is active only when in the Curve Type field.

   B. **<F2:Calibrate>** is active only when in either the Standard field or in one of the Sec/me column entry fields.

   C. **<F3:Curve>** is active only when in one of the Sec/mE column entry fields.

   D. **<F3:Graphic>** is active only when calibrating.

3. Enter the concentrations of the calibration curve into the value column. The standard with the highest concentration must be in position 1. Determine the concentrations that you want to use for the calibration. The instrument prepares all dilutions as they relate to Standard 1. For example: The concentration of Standard 1 is 100%. You want Standard 2 to be 80%. Enter 80 into the Standard 2 position. The instrument will prepare the dilution using 80 parts of Standard 1 and 20 parts of diluent.

   19.2.2

   The calibration curve should span the reportable range. Note that if the "Dilution r" is set to 2 or above, all measured values that yield times either above or below the curve limits will be automatically rediluted using a higher or lower dilution as appropriate. The sample volume must be set to an even number that when divided by 2 will be above the 3 µL minimum redilution sample volume (at least 6 µL). This automatically extends the reportable range to twice the concentration of Standard 1 and ½ the concentration of the last standard (Max. value setting = Standard 1 value x 2). **The "Dilution r" parameter should be set to "0" if the reaction is directly proportional (time increases with increasing concentration or time decreases with decreasing concentration).**

4. Move the cursor into the Sec/mE column. Note that during Test Parameter definition, arbitrary consecutively increasing or decreasing numbers must be

entered into this column. If no numbers are entered, a procedural error message will not allow exit from the Test Parameter screen.

When performing a calibration, it doesn't matter what is in the Sec/mE column. Any numbers will be automatically replaced by the measured values during calibration.

<F2:Calibrate> is active when in the Sec/mE value column. Press **<F2>** to begin the calibration process.

5. The “Calibrate” screen appears:

```
Automatic
dilution ? NO
```

Confirm that you want automatic dilution by pressing **<y><Enter>**.

6. The “Calibrate” positioning screen appears:

```
Position:30   : Buffer
Position: 1   : Std<100>
Position: 2   : Tube
Position: 3   : Tube
Position: 4   : Tube
Position: 5   : Tube

Confirm: NO
```

Dilutions are automatically prepared using a combination of Standard 1 and an appropriate buffer placed into position 30 of the Sample Tray. The final total volume of the dilution is always 0.4 mL (400 µL).

Place appropriate buffer into position 30, the reference material into position 1, and empty tubes in all remaining indicated positions.

7. When buffer, reference material and empty tubes are in place, confirm with **<y><Enter>**. Calibration will begin. The screen will say: “Wait . . . “.
8. The calibration process may be aborted at any time after dilutions have been prepared and “Wait . . .” is being displayed. To abort, press **<Esc>**. The “Abort confirmation” screen will appear. To abort, respond to “Confirm: NO” with **<y><Enter>.** To continue calibration, press **<Enter>**.
9. All calibration is performed in duplicate.
10. During calibration, the reaction progress for tests performed using the optical measuring mode may be viewed by pressing **<F3:Graphic>** to enter the graphic mode. Follow instructions at the bottom of the graphics window. Press **<Esc>** to return to the “Calibration” window. Note that once the graphic mode is activated by pressing **<F1>**, it will remain active for all subsequent measurements until **<F6>** is pressed to deactivate the graphic mode.

11. When calibration is completed, the calibration results will be displayed.

```
36.3  36.3    36.3 CV: 0.0
39.9  40      39.9 CV: 0.2
44.2  44      44.1 CV: 0.3
48.7  49.1    48.9 CV: 0.6
54.1  53.9    54   CV: 0.3
press any key
```

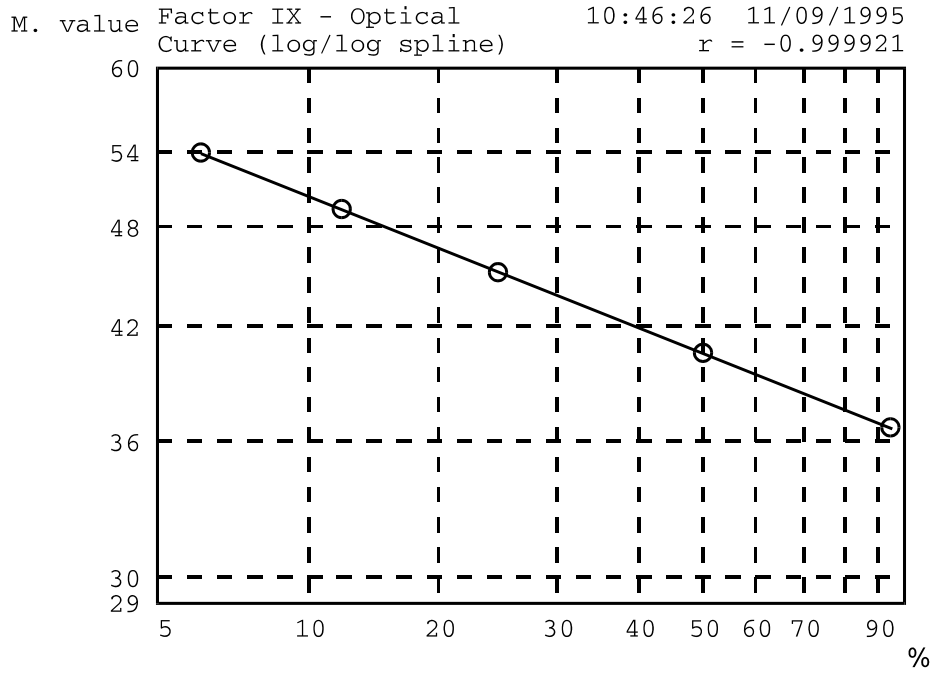
ATTENTION!
Calibration statistical data is not stored. Only the average time/mE is stored. Printout of the calibration screen and test parameters associated with the calibration is recommended.

Measured value 1, measured value 2, average value and the CV of the duplicates is displayed. This is the only time that you will be able to obtain a hard-copy of the measured values and the duplicates CV. Press **<Print Scrn>** to print the calibration results screen.

Press **<any key>** to return to the Calibration parameters screen. The averaged values will be automatically inserted into the Sec/mE column. This screen may be printed when exiting the Test Parameters screen. Update hard-copy file with the printed out calibration results screen and the updated parameter printout.

All entries in the value column (concentrations) must be opposed by a measured value in column two (time or mE). Exit from the Test Parameters screen will not be permitted if there are unopposed values.

12. The calibration curve may be examined by pressing **<F3>** when the cursor is in the Sec/mE column.



Calibration - Curve	
Item	**Description**
Factor IX - Optical	Test name.
Curve (log/log spline)	Curve type as defined by "Curve Type" parameter.
10:46:26 11/09/1995	Time and date graph printed.
r = -0.999921	Calculated correlation coefficient for the calibration curve.
M. value	Y-axis. Measured values. Time or mE.
%	X-axis. Concentration values.

The curve type may be changed to allow viewing of the calibration curves using different types. Move the cursor to the Curve Type field and press **<F1>** to bring up the Curve Type listing. Move cursor to the type you want to try and press **<Enter>**. Move the cursor back to the Sec/mE column and press **<F3>** again. The curve using the new type is displayed.

13. The new calibration curve will be applied to all new results. Results completed prior to calibration will not be recalculated.

22.2 Manual Dilution

The procedure for "manual" dilutions is the same as above except that the dilutions are already prepared when starting the calibration process. These dilutions may be prepared manually off-line or they may be dilutions that the instrument has already prepared.

1. Enter concentrations into the value column that are appropriate to the prepared dilution. Enter as consecutive numbers.
2. Press **<F2>** to begin the calibration process.
3. The "Calibrate" screen appears:

```
Automatic
dilution ? NO
```

Confirm that you do not want automatic dilution by pressing **<Enter>**.

4. The "Calibrate" loading screen appears:

```
Load tray
and confirm  YES
```

Place prepared dilutions into the sample tray.

5. When prepared dilutions are in place, confirm with **<Enter>**. Calibration will begin. The screen will say: "Wait . . .".
6. Continue as outlined above in steps 8 through 13 of the Automatic Dilution procedure.

22.3 Single-Point Calibration

Calibration can be done using a single point. It is used when measured time results are reported as a ratio to a standard time. Position the cursor in the “Standard” field. Place reference material into Sample Tray position 1. Press **<F2>** to begin the calibration. When calibration is completed, the averaged time will be inserted into the “Standard” field. If calculation of a ratio is desired, enter **<1.0>** into the “ISI-Factor” field. To report the calculated ratio, enter **<R>** in the “Data reduction” section.

22.4 Derived Fibrinogen

Calibration of the Derived Fibrinogen test is **not** performed while in the Derived Fibrinogen calibration screen. A calibration curve is generated by measuring the optical-PT. Optical-PT must defined in position 1 of the Test List and certain prerequisite conditions must be met (See Chapter 19, Section 19.2.8). Best correlation will be obtained using fresh patient plasma, with Clauss-established fibrinogen values, as standards. The samples selected as standards should span the reportable range. The Clauss-fibrinogen concentration is entered into the value column in the Derived Fibrinogen calibration section. After measuring these plasmas in duplicate as optical-PT´s, enter the averaged mE Value opposite the corresponding concentration in the Sec/mE column of the Calibration Section of the Derived Fibrinogen test definition.

19.2

23 MAINTENANCE 23-1
23.1 SERVICE OUTLINE 23-1
23.2 DAILY MAINTENANCE 23-3
23.2.1 Clean Probe Exterior 23-3
23.2.2 Fresh Water Check 23-3
23.2.3 Waste Fluid Disposal 23-4
23.2.4 System Wash 23-4
23.2.5 Hydraulic System Leak Check 23-5
23.2.6 Used Cuvette Disposal 23-5
23.2.7 Cuvette Cassette Disposal Area Check 23-5
23.2.8 General Housekeeping 23-6
23.3 WEEKLY MAINTENANCE 23-7
23.3.1 Hydraulic System Cleaning 23-7
23.3.2 Dust Filter Cleaning 23-8
23.3.3 Incubation Rail and Wash/Rinse Well Cleaning 23-8
23.3.3 Coolant Level Check 23-9
23.4 MONTHLY MAINTENANCE 23-10
23.4.1 Syringe Cleaning 23-10
23.4.2 Cleaning of Photometric Measuring Wells 23-10
23.5 MISCELLANEOUS UNSCHEDULED MAINTENANCE 23-11
23.5.1 Photometer Calibration 23-11
23.5.2 Volume Check 23-13
23.6 REPLACEMENT PROCEDURES 23-14
23.6.1 Photometer Lamp 23-14
23.6.2 Syringe/Plunger Assembly 23-15
23.6.3 Syringe Plunger Tip and O-Ring 23-15
23.6.4 Tubing 23-16

23.1 Service Outline

Classification	Frequency	Task	Section
Maintenance	Daily	Clean Probe Exterior	23.2.1
		Fresh Water Check	23.2.2
		Waste Fluid Disposal Check	23.2.3
		System Wash	23.2.4
		Hydraulic System Leak Check	23.2.5
		Used Cuvette Disposal Check	23.2.6
		Empty Cuvette Cassette Disposal	23.2.7
		General Housekeeping	23.2.8
	Weekly	Hydraulic System Cleaning	23.3.1
		Dust Filter Cleaning	23.3.2
		Incubation Rail Cleaning	23.3.3
		Wash/Waste Station Cleaning	23.3.4
		Coolant Level Check	23.3.5
	Monthly	Syringe Cleaning	23.4.1
		Photometric Wells Cleaning	23.4.2
	As Necessary	Photometer Calibration	23.5.1
		Volume Check	23.5.2
Replacement	As Necessary	Photometer Lamp	23.6.1
		Syringe/Plunger Assembly	23.6.2
		Syringe Plunger Tip and O-Ring	23.6.3
		Tubing	23.6.4

MONTH _____ **YEAR** _____ **SERIAL NUMBER** _____

		DAILY							WEEKLY					MONTHLY	
	TECH INITIAL	CLEAN PROBE	CHECK FRESH WATER	CHECK LIQUID WASTE	SYSTEM WASH	LEAK CHECK	CHECK CUVET WASTE	CLEAR EMPTY CASSETTES	DISINFECT	CLEAN FILTER	CLEAN INC. RAIL	CLEAN WASH WELL	CHECK COOLANT	CLEAN SYRINGE	CLEAN OPTICS
1															
2															
3															
4															
5															
6															
7															
8															
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29															
30															
31															
REVIEW															

23.2 Daily Maintenance

23.2.1 Clean Probe Exterior

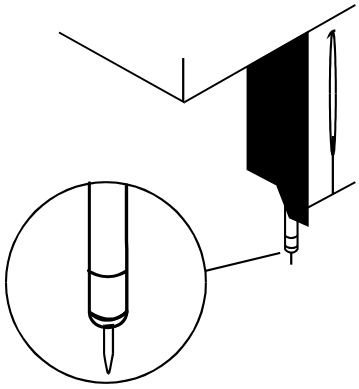
Optimum reagent delivery as a clean dispense with no wicking is dependent on having a clean probe exterior.

A. Move probe out of the wash well.
<Measure><Robot right>

B. Carefully wipe probe tip and lower body with gauze moistened with reagent alcohol.

C. Perform a system wash to remove any residual alcohol.

NOTE: Performing a system wash is part of the daily recommended maintenance. It is also recommended after replacement of fresh water. It only needs to be done once. A system wash performed at any point in the daily maintenance will satisfy the post-probe-cleaning wash requirement.



23.2.2 Fresh Water Check

Check the supply of fresh DI water. Replenish as necessary. If using water from a pressurized DI source, best performance is attained using degassed water. The easiest way to degas water is to let it sit for a minimum of 8-12 hours. It is convenient to have an extra 21 L container that may be filled ahead of time and be degassed by the time it is needed.

A. Unscrew the cap of the fresh water container. Do not disconnect the sensor and tubing system. Care should be taken to turn only the ridged cap and not the central tubing connection area.

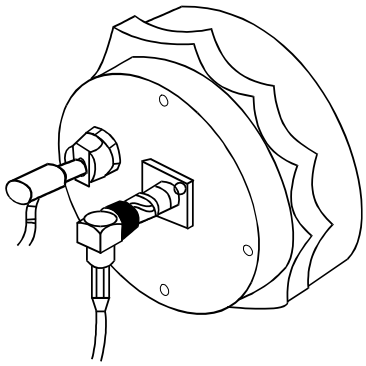
B. Remove sensor and tubing. Carefully lay aside on paper towels.

C. Fill with DI water. If a base cabinet is in use, the fill volume should not be above the bottom of the lid when the bottle is positioned on its side with the lid to the top.

D. Replace sensor and tubing.

E. Tighten cap. Care should be taken to turn only the ridged cap and not the central tubing connection area.

F. To remove any air introduced into the system, a system wash should always be performed any time the sensor and tubing assembly have been removed from the container.



23.2.3 Waste Fluid Disposal

A. Unscrew the cap of the waste container. Do not disconnect the sensor and tubing system. Care should be taken to turn only the ridged cap and not the central tubing connection area.

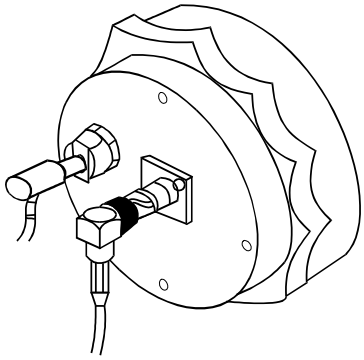
B. Remove sensor and tubing. Carefully lay aside on paper towels.

C. Dispose of waste fluid.

D. Rinse with tap water.

E. Replace sensor and tubing.

F. Tighten cap. Care should be taken to turn only the ridged cap and not the central tubing connection area.



WARNING!
Potentially biohazardous material. Discard according to laboratory safety policies.

Addition of a concentrated biohazardous waste disinfectant is recommended (such as Lysol® IC™ Brand Quaternary Disinfectant Cleaner or equivalent quaternary ammonium disinfectant). Add the amount of concentrated disinfectant recommended by the manufacturer to effect disinfection of biohazardous materials (e.g., a l:256 dilution of Lysol® IC™ is recommended by the manufacturer. When the waste container is full, it will contain approximately 19 L of waste fluid. 19000/256 = 74 mL. The addition of approximately 75 mL of concentrated Lysol® IC™ will effectively decontaminate the contents of a full waste container.)

Lysol® IC™ is a registered trademark of National Laboratories, L&F Products, Montvale, NJ 07645

23.2.4 System Wash

Optimum performance is dependent on having an uncontaminated sample and reagent dispense system. Daily performance of a three-cycle system wash assures that the system will remain uncontaminated.

14.2

To set the number of wash cycles to 3, press **<Service><Wash><Enter><Enter>**

A window opens which allows entry of the desired number of wash cycles to be performed.

```
Number of cycles ; 1
```

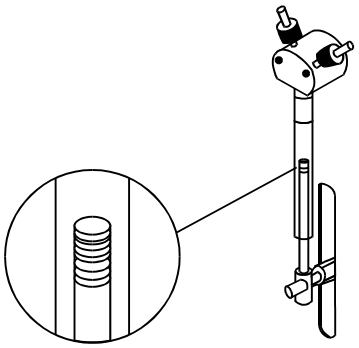
Press **<3><Enter>**.

Three (3) wash cycles will be performed.

23.2.5 Hydraulic System Leak Check

A. During the wash cycles, the lines leading to and from the syringe are visually examined for bubbles and air gaps. If bubbles are observed, flick the tubing during the wash process to move the bubbles into the syringe so that they will be pumped out through the probe. Repeat if large bubbles or air gaps persist.

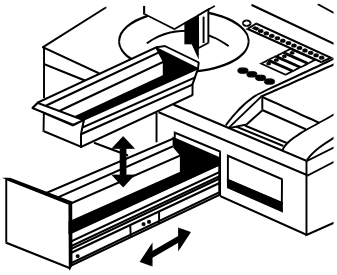
   A few small bubbles are not a cause for alarm although their presence may suggest that the syringe needs to be cleaned or replaced.



B. Visually observe the Teflon plunger tip for bubbles or residue accumulation on top of the tip or in the threads. Clean as necessary.

C. Check for fluid leakage between the plunger and syringe barrel. The plunger exiting from the glass syringe barrel should be dry. Replace as necessary.

23.2.6 Used Cuvette Disposal



A. Open waste drawer

B. Remove waste container

C. Remove disposable liner

D. Dispose of filled liner

E. Replace with new disposable liner

WARNING!
Potentially biohazardous material. Discard according to laboratory safety policies.

23.2.7 Cuvette Cassette Disposal Area Check

When cuvette cassettes are empty, they are transported off the back of the chute and fall to the lower level of the cuvette chute. A belt transport system carries the empty cassettes forward in the chute. If cassettes are not cleared from the lower chute, newly empty cassettes cannot be cleared from the upper chute. A sensor will sound the alarm if cuvette cassettes accumulate in the chute. The status area will have a flashing “Tray waste” in a red field.

Tabletop instrument: Empty cuvette cassettes are manually cleared from the chute on a regular basis. No more than four (4) cassettes should be allowed to accumulate in the chute. How often the chute area needs to be checked is dependent on workload. As a rule, when new cassettes are added, empty cassettes should be removed from the chute. Lift the swinging door, reach into the chute and remove any accumulated cassettes. Check the length of the lower chute area for plastic or other debris. Discard according to laboratory policies. The cassettes are recyclable.

Base-mounted instrument: Instruments installed with the optional base have an opening in the cassette waste chute. Cuvettes travel down the chute, fall through

the opening into a large cassette disposal container. Check the large disposal area daily. The cassettes are recyclable plastic. Check the length of the lower chute area for plastic or other debris. Discard according to laboratory disposal policies.

23.2.8 General Housekeeping

A. Clean up spills as they occur. Use only water, alcohol or mild soap solution.

WARNING!
Harsh abrasives, bleach or other solvents may result in permanent cosmetic damage. Water or other fluids leaking into electronic areas may result in a short circuit.

B. Remove reagents and Enzyclean. Expired reagents should be discarded. To avoid contamination and the effects of concentration, reagents (including Enzyclean) should be stored capped when not in use. If pouring Enzyclean into the trough, remove trough. Discard any remaining Enzyclean. Rinse trough. Reposition in trough well.

C. Dispose of processed samples.

WARNING!
Potentially biohazardous material. Discard according to laboratory safety policies.

23.3 Weekly Maintenance

23.3.1 Hydraulic System Cleaning

Disinfecting and rinsing the tubing and probe system weekly eliminates residue accumulation and water-borne microbial contamination.

A. Prepare 100-200 mL of disinfectant solution in a 500 mL graduated cylinder or other container large enough for the tubing and sensor system to fit into. The same concentrated disinfectant used for decontaminating the waste container may be used to prepare working strength disinfectant. Since the tanks and tubing are not exposed to biohazardous materials, a more dilute solution that is still effective for water-borne microorganisms is used. A more dilute solution is easier to rinse out of the system. Use a dilution twice that recommended by the manufacturer for biohazardous waste decontamination (e.g., a 1:256 dilution of Lysol® IC™ is recommended for biohazardous waste decontamination. A 1:512 will be effective for system disinfection. For ease in preparation, use a 1:500 dilution. Add 200 µL of Lysol® IC™ to 100 mL deionized water.) If the hydraulic system is known to be heavily contaminated, use the manufacturer's recommended decontamination concentration.

   Lysol® IC™ is a registered trademark of National Laboratories, L&F Products, Montvale, NJ 07645

B. Unscrew the cap of the fresh water container. Do not disconnect the sensor and tubing system. Care should be taken to turn only the ridged cap and not the central tubing connection area.

C. Remove sensor and tubing and insert assembly into the diluted disinfectant container.

D. **<Service><Wash><Enter><Enter><3><Enter>**

The instrument will go through 3 wash cycles pumping approximately 24 mL of disinfectant solution into the system. Allow disinfectant to remain in the system for 5-10 minutes before proceeding.

E. Remove suction tube and sensor assembly from the disinfectant container. Rinse with DI water and carefully set aside. Discard remaining disinfectant solution. Rinse container thoroughly with DI water. Fill container with DI water and reinsert the suction tube and sensor assembly.

<Service><Wash><Enter><Enter><10><Enter>

F. The instrument will go through 10 wash cycles pumping approximately 80 mL of DI water through the system.

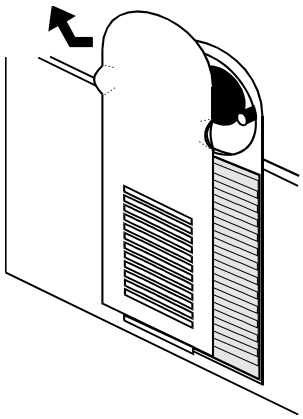
G. At the completion of the wash cycles, remove assembly from the rinse container and re-insert into the fresh water container.

H. **<Service><Wash><Enter><Enter><3><Enter>**

Any air introduced into the lines is removed. Observe lines leading to and from the syringe to assure that no large bubbles or air gaps are left at the end of the wash cycles. If large numbers of bubbles persist, repeat as necessary.

23.3.2 Dust Filter Cleaning

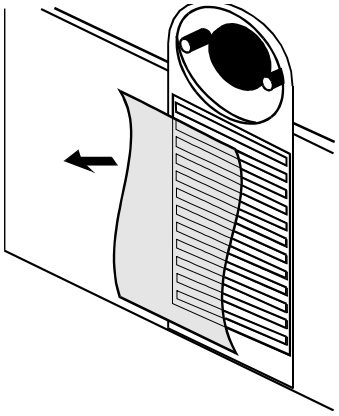
A filter covering the air intake protects the internal parts of the instrument from dust accumulation. Excessive accumulation of dust and dirt on the filter may result in insufficient cool air intake causing overheating and ultimate instrument failure. The filter is located behind a grilled cover on the lower back left side of the instrument.



A. Grasp ears and lift cover out and up. Set cover aside.

B. Lift filter off to remove.

C. Shake out any loose dust. Rinse in running tap water. Squeeze gently to express water. Place between paper towels. Press to remove any remaining water. If excessively dirty, a mild soap solution may be used. Rinse well and remove residual water as described above. Replace filter if torn or if no longer able to clean (S9303).



D. Reposition dry filter over the air intake.

E. Replace cover

23.3.3 Incubation Rail and Wash/Rinse Well Cleaning

Regular cleaning of the incubation rail will avoid buildup of dirt and debris that may result in erratic progression of cuvettes along the rail. This may ultimately lead to cuvette jams. Regular cleaning of the wash/rinse well prevents fungus growth from occurring in the well area and drain tubing. This may ultimately lead to inadequate drainage of the wash/rinse well.

A. With the power off, **gently** move the robot arm to the right side and position forward of the incubation rail.

WARNING!
Move the robot arm gently to the extent of travel position. A forceful stop may result in robot arm misalignment.

B. Remove cover over the incubation rail by lifting up from the left end.

C. Using tweezers, remove cuvettes in the rail area.

D. Using tweezers, remove any bits of plastic or other debris. Use a small magnet to remove any stray steel balls.

E. Using a swab wetted with alcohol, clean the floor and sides of the rail area.

F. Examine the underside of the incubation rail for signs of splattering of either reagent or sample. If splattering is apparent, the dispense rates may be too forceful or the alignment may be incorrect. Remove any splatter with an alcohol wetted gauze pad.

G. Using a transfer pipette, dispense approximately 1 mL of 20% bleach solution into the well. Alternately aspirate and dispense solution several times. Do not splash into the incubation rail area. Use a swab to clean around the sides, the rinse well area and the metal sensor (looks like a metal button) near the top rear of the well. Remove any remaining bleach solution with the transfer pipette and discard.

H. Rinse in the same manner with deionized water. Remove excess water with the pipette.

I. Replace incubation rail cover.

J. Power the instrument up following the usual power-up procedure.

K. To fill the incubation rail with cuvettes, press **<Service><Transfer cup><Enter>**.

L. Assure that all residual bleach is removed by performing three system washes. **<Service><Wash><Enter><Enter><3><Enter>**.

NOTE: This procedure may be performed with the power on by using the Robot Right function. Care must be taken to avoid accidentally returning the robot to the home position over the wash well before the procedure is completed.

23.3.3 Coolant Level Check

The coolant gauge is located on the left side of the back of the instrument (when facing the front of the instrument). There is a chrome filler tube at the left top side of the back of the instrument. Observation of the gauge is not an effective monitor of the coolant status. If the gauge shows more than a tiny bubble at the top, the coolant level is usually seriously low. A more reliable index is to unscrew the cap on the chrome filler tube and look down into the tube. Coolant should be just visible at the bottom of the filler tube. Replenish as necessary using the Sigma Diagnostics AMAX 200 Plus/AMAX 400 Plus coolant solution (Catalog #: A4969).

23.4 Monthly Maintenance

23.4.1 Syringe Cleaning

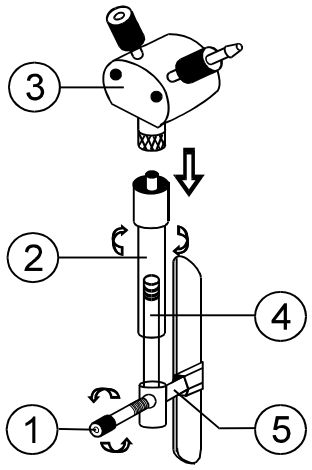
The syringe should be cleaned monthly or as necessary if bubbles or residue accumulation is observed on the syringe tip.

A. <Service><Move syringe>

B. The syringe plunger will move down to a mid position that allows disassembly.

C. Unscrew and remove piston screw (1) by turning knurled knob counter-clockwise.

D. Unscrew syringe barrel from the valve assembly by turning counter-clockwise. Pull glass syringe barrel (2) down to detach from valve assembly (3). Carefully remove syringe and plunger (4) from the connecting rod (5) by pulling straight out.



E. eparate plunger and barrel and immerse both in a container of reagent alcohol. Allow to soak for 5-10 minutes.

F. Using gauze or other lint-free absorbent material, clean plunger tip and threads to remove any residue accumulation.

G. Rinse barrel and plunger in DI water. To avoid damage to plunger seal during reassembly, leave a small amount of water in the barrel.

H. Reassemble barrel and plunger. The plunger should fit snugly.

I. Re-attach barrel and plunger assembly to the connecting rod.

J. Pull barrel straight up to engage the valve assembly. **Hand-tighten** by turning clockwise to screw onto the valve assembly.

WARNING!
Hand-tighten only. Do not over tighten. Over tightening can cause irreparable damage to the valve threads.

K. Reposition piston screw and tighten by turning knurled knob clockwise.

L. Perform a system prime or wash to remove air introduced into the system.

23.4.2 Cleaning of Photometric Measuring Wells

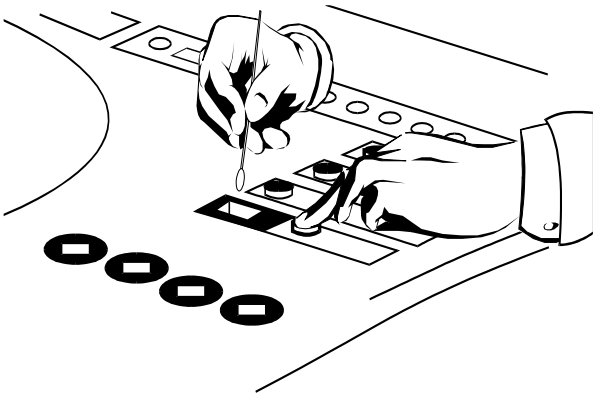
Accumulation of residues or dust may cause large result variances between the four measuring optical wells. During photometer calibration, large variances between the measured blank and air values will also be observed.

A penlight or other suitable flashlight will be needed.

A. Moisten a swab with water/alcohol (50 %) solution. The swab should not be dripping. Roll on a paper towel to remove excess water/alcohol (50 %) solution.

B. Pull back the cover over one of the optical measuring wells.

C. There will be a cuvette in the well. Using the stick end of the swab, push the cuvette down through the bottom of the measuring well.



D. The optical lenses are located approximately 35-40 mm below the surface of the well on both the right and left sides. Use a flashlight to assist in locating the lenses. Carefully insert swab and gently wipe the surface of the left and right lenses. Take care to avoid getting the swab tangled in the spring clips located on the top front and left sides of the well.

E. If the swab becomes noticeably dirty, repeat with a clean moistened swab.

23.5 Miscellaneous Unscheduled Maintenance

23.5.1 Photometer Calibration

Password security system = Service password
PIN security system = Level 4 access; Levels 0, 1 and 2 prohibited.

The photometer calibration procedure checks the air and blank values. Because the photometer is critical to instrument performance, the area is protected by a service password. No actual adjustments are done automatically either during or as a result of the "calibration" procedure. The calibration procedure only measures and displays the air, dark current and blank values. Its primary use is as a trouble-shooting tool. All output adjustments must be performed by a Sigma-Amelung authorized service representative.

If being performed after cleaning the photometric measuring wells, assure that the lenses are dry. Use a dry swab to remove any residual moisture.

Password security: **<Service><Calibrate Photometer><Service Password>**
PIN security: **<Level 4 sign-on><Service><Calibrate Photometer>**

A confirmation screen will be displayed.

```
Measure air value ?
Confirm  NO
```

Confirm request with **<y><Enter>**

```
please wait ...
Empty channels
```

```
please wait ...
Turn lamp off
```

The optical measuring channels are emptied and the lamp is turned off.

```
please wait . . .
Dark measure
```

```
Air values:
Channel 1  96.0%  8
Channel 2  96.2%  5
Channel 3  94.1%  2
Channel 4  96,8%  5

please wait . . .
Turn lamp on
```

or

```
Air values:
Channel 1  99.2%   2
Channel 2  98.9%  10
Channel 3  98.5%   0
Channel 4  99.6%  12

please wait
Turn lamp on
```

```
Air values
Channel 1  96.0%  8
Channel 2  96.2%  5
Channel 3  94.1%  2
Channel 4  96.8%  5

Values are normal
Measure blank values? NO
```

or

```
Air values
Channel 1  99.2%   2
Channel 2  98.9%  10
Channel 3  98.5%   0
Channel 4  99.6%  12

Air values out of range
Measures blank values? YES
```

An evaluation of the air value and dark current results and a request for confirmation to perform of measurement of the blank values is displayed.

Dark current values must be > 0 and < 10.

If the evaluation was normal, press **<y><Enter>** to continue with the measurement of the blank values. If the evaluation is not normal, press **<Enter>** to continue with the measurement of the blank values.

```
Air values:
Channel 1  96.0%  8
Channel 2  96.2%  5
Channel 3  94.1%  2
Channel 4  96.8%  5

please wait . . .
Load channels
```

or

```
Air values:
Channel 1  99.2%   2
Channel 2  98.9%  10
Channel 3  98.5%   0
Channel 4  99.6%  12

please wait . . .
Load channels
```

Cuvettes are transferred into the optical measuring wells.

```
Blank values:
Channel 1  97.3%
Channel 2 106.0%
Channel 3  92.0
Channel 4  95.7%

press any key
```

or

```
Blank values:
Channel 1  95.0%
Channel 2  75.3%
Channel 3  98.6%
Channel 4  77.1%

press any key
```

At the completion of the blank calibration procedure, the percentage transmission figures are displayed. All values must be in excess of 80%. Press any key to exit.

If unable to achieve acceptable air and blank values, cleaning of the optical measuring wells is indicated (Section 23.4.2). Repeat calibration after cleaning optical wells.

If the values are still unacceptable after cleaning the wells, replacement of the lamp is indicated (Section 23.6.1).

If after replacement of the lamp, the values are still unacceptable, contact Sigma Diagnostics Technical Service (800-325-0250). All output adjustments must be performed by a Sigma-Amelung authorized service representative.

23.5.2 Volume Check

A. Remove 10 clean cuvettes with balls from a cuvette box. Weigh cuvettes with balls to obtain an average weight.

B. **<Service><Check volumes>**
The "Check volumes" dialog window is displayed.

```
Volume   :100

Replicate :5

Confirm:  NO
```

C. Enter the volume to be checked and the number of times it will be checked. Confirm with **<y><Enter>**.

```
Place a full tube in
position #1 of the
sample holder.

press any key
```

D. Place a tube of water into position #1 of the Sample Tray.

E. Press **<any key>** to initiate the "Check volumes" procedure. Water will be aspirated from the tube and dispensed into the specified number of cuvettes in the cuvette rail. After dispensing is completed, the robot will go to the right and park.

F. A cuvette containing the dispensed volume will be ejected from the cuvette transfer position every time **<any key>** is pressed. Catch each cuvette as it is ejected

G. Weigh dispensed cuvettes with balls to obtain an average dispensed weight. Subtract the average empty-weight from the average dispensed-weight to obtain the average dispensed water weight. 1 ml of water weighs 1 gm. The calculated volume should be within $\pm$ 5% of the entered volume.

H. If the calculated volume is out of range, replace the syringe (Section 23.6.2). Recheck volumes. If still unacceptable, replace the tubing (Section 23.6.3).

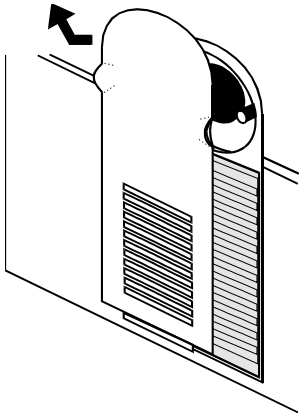
23.6 Replacement Procedures

23.6.1 Photometer Lamp

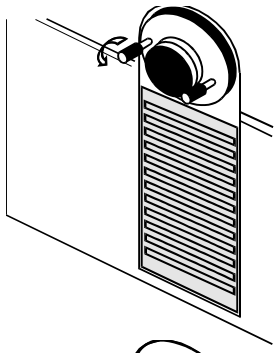
The photometer lamp (Catalog # A3335) is located in the lower back left side of the instrument. Access is gained by removing a cover plate.

A. **<End><Yes>:** AMAX operating program is exited. Power down AMAX 200.

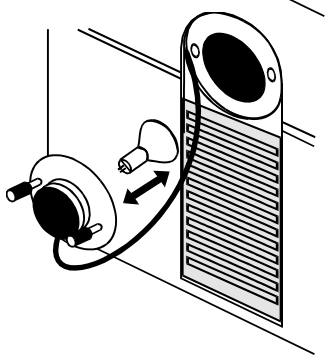
B. Grasp ears and lift cover out and up. Set cover aside.



C. Loosen the two screws holding the lamp assembly in place. Turn the screws counter-clockwise.



D. Pull the lamp assembly straight out taking care not to pull on the power cable.



E. Remove the lamp from the assembly by pulling straight out.

WARNING!
Lamp may be hot!!! Wrap lamp with protective heat absorbing material.

F. Replace with a new lamp. **Do not touch the lamp or the reflective shield with bare hands**. Fingerprints leave an oily residue that may degrade lamp performance and the reflective capabilities of the shield. If touched inadvertently, wipe with an absorbent lint-free tissue moistened with reagent alcohol.

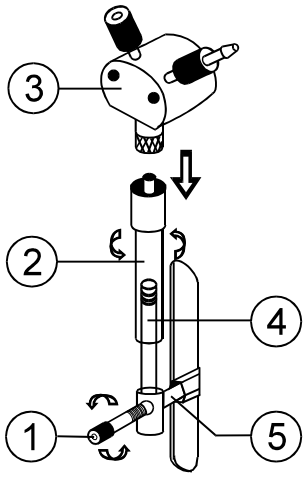
G. Reassemble in reverse order.

H. Perform photometer calibration to assure that blank and air values are acceptable.

23.6.2 Syringe/Plunger Assembly

The syringe and plunger assembly (A1958) should be replaced if water leakage is observed or if large bubbles and air gaps persist after repeated prime/wash cycles or after replacement of the plunger tip and o-ring (See Section 23.6.3).

A. **<Service><Move syringe>**
The syringe plunger will move down to a mid position that allows disassembly.



B. Unscrew and remove piston screw (1) by turning knurled knob counter-clockwise.

C. Unscrew syringe barrel from the valve assembly by turning counter-clockwise. Pull glass syringe barrel (2) down to detach from valve assembly (3). Carefully remove syringe and plunger (4) from the connecting rod (5) by pulling straight out.

D. Moisten the inside of the new syringe by aspirating approximately 100 µL DI water into the syringe.

E. Attach new syringe barrel and plunger assembly to the connecting rod.

F. Pull barrel straight up to engage the valve assembly. **Hand-tighten** by turning clockwise to screw onto the valve assembly.

WARNING!
Hand-tighten only. Do not over tighten. Over tightening can cause irreparable damage to the valve threads.

G. Reposition piston screw and tighten by turning knurled knob clockwise.

23.6.3 Syringe Plunger Tip and O-Ring

A. Remove the syringe/plunger assembly as described in section 23.6.2, steps A through C.

B. Remove the plunger from the syringe. Place on a hard surface.

C. Using a sharp blade, slice the plunger Teflon tip vertically. Remove the tip and O-ring.

D. Place a new O-ring (O3015) onto the end of the plunger.

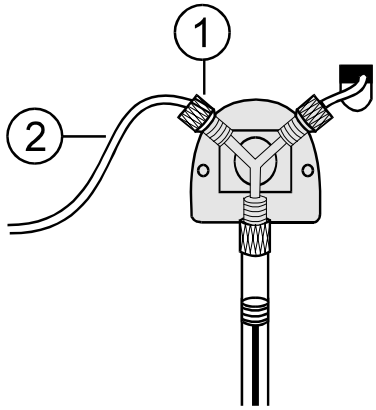
E. Position a new Teflon tip (S9178) over the end of the plunger. Carefully invert the plunger and tip vertically over the counter top or other hard surface. Seat the new tip on the plunger by pressing the tip on the counter top.

F. Moisten inside of syringe barrel and replace plunger.

G. Reassemble as described in section 23.6.2, steps E through G.

23.6.4 Tubing

A. **<End><Yes>**
AMAX operating program is exited. Power down AMAX 200.

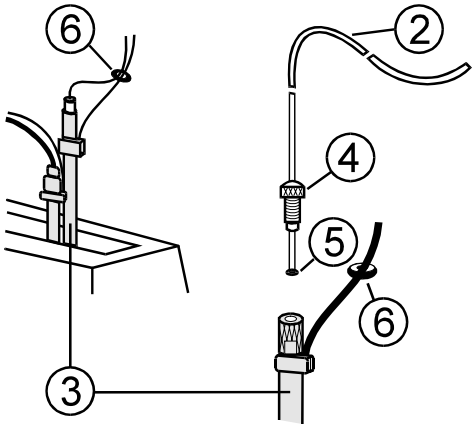


B. Place a protective covering of paper towels or other absorbent material over the right-hand top of the instrument. Cover incubation rail and measuring well areas.

C. Loosen and remove the left-hand connector (1) on the syringe valve by turning counter-clockwise.

D. Pull tubing (2) out of the valve connector.

E. Loosen and remove the tubing connector (4) located on the top of the probe (3).



F. The probe end of the tubing has a flange (5). Pull unflanged end of the tubing (2) out through the probe connector.

G. Detach tubing from the retainer rings (6) that hold all the tubing together.

H. Push new tubing into both connectors.

I. Pull flanged end of tubing up to bottom of connector. Screw connector to the probe by turning clockwise. Hand tighten only. Do not over tighten.

J. Screw valve connector to the valve by turning clockwise. Hand tighten only. Do not over tighten.

K. Power instrument on.

L. **<Service><Wash>**

M. Check all fittings for leakage. Wash or prime as necessary to remove large bubbles and air gaps.

24 QUALITY ASSURANCE.....24-1
24.1 PATIENT SAMPLE 24-1
24.2 REAGENTS 24-1
24.3 INSTRUMENT MECHANICS 24-1
24.4 TEST PARAMETERS 24-2
24.5 MEASUREMENT ANALYSIS 24-2
24.6 RESULTS 24-2

Quality Assurance is the process of monitoring each parameter known to affect the quality of reported results. The AMAX 200 has incorporated monitors in all aspects of the system: patient sample, reagents, instrument mechanics, test parameters, measurement analysis and results.

The AMAX 200 supports quality assurance in two ways: (1) by alerting the operator of conditions that could be precursors to errors; and (2) by early detection of critical operating errors. Wherever possible, monitoring is done with sensitive mechanical function checks that may indicate a system variance before it becomes large enough to be detected by traditional biological quality control methods.

24.1 Patient Sample

An integrated barcode scanner provides the option of positive patient identification. Each barcode is scanned initially at the start of processing and is rescanned immediately prior to processing each sample batch thus ensuring positive patient ID. For maximum flexibility, keyboard entry of samples is also an option. Duplicate sample ID entry is not permitted. The sample and all associated results are associated by the unique sample ID. Stat samples are incorporated into the processing cycle on command thereby permitting rapid turn-around-time for time-critical samples. A level sensor assures that sample is present.

24.2 Reagents

Reagent levels are constantly monitored thereby assuring a continuing supply of essential reagents. An audible alert and flashing message notifies the operator when reagent levels are below minimum operating volumes. Processing for tests using the reagent will be discontinued unless reagent is replenished.

An on-board Quality Control program is available to evaluate results thereby assuring acceptable reagent performance. Once accepted, control results cannot be deleted thereby resulting in a factual record of test performance.

24.3 Instrument Mechanics

Critical operating parameters are constantly monitored. These include monitoring of all temperature-controlled modules, lamp status and condition, adequacy of system fluids, and cuvette supply. The status of all critical modules is constantly displayed.

All temperature modules have set warning and stop limits. An audible alert and flashing message will notify the operator when warning limits have been exceeded. If the temperature exceeds the stop limits, processing is aborted.

The lamp status and condition is constantly monitored. Any lamp failure results in immediate termination of processing.

The fresh water supply is constantly monitored and a sensor system notifies (audible alert and flashing message) the operator when the fresh water supply has dropped below set limits. Processing is terminated if the fresh water supply is not replenished.

The accumulation of waste fluid is constantly monitored and a sensor system notifies (audible alert and flashing message) the operator when the waste fluid container needs to be emptied. Processing is terminated if the waste container is not emptied.

The supply of cuvettes is monitored and the operator is notified (audible alert and flashing message) if the supply falls below minimum requirements. Processing is terminated if the supply of cuvettes is not replenished.

Automatic wash cycles assure system cleanliness at all times. Programmed wash cycles eliminate cross-contamination and carryover effects. During processing, the probe is washed after aspirating sample and/or reagents. Washing includes not only the inside of the probe but also the outside of the probe tip. If appropriate, a cleaning solution may be added to the wash cycle.

24.4 Test Parameters

During programming of test parameters and during calibration, parameters are cross-checked to assure lack of conflict. Programmed reagent volumes are checked to assure that they are above the required minimum total reaction volume. Dilution protocols are checked to assure that the programmed volumes match the dilution ratio. The operator will be notified by a red flashing field when a procedural error is present.

24.5 Measurement Analysis

The AMAX 200 offers alternative measurement methods that may be used to offset adverse sample conditions that disallow measurement by one method or the other. The instrument is capable of measurement by mechanical and optical methods. Use of mechanical measurement of the clotting endpoint provides a means of measuring according to traditional principles and reduces the effects of hemolysis, icterus and lipemia. Optical measurement is used for detection of clotting endpoint and enzyme activity analyses. Clotting endpoint is measured as a rate of change from a baseline value thereby reducing the effects of hemolysis, icterus and lipemia. Enzyme analysis is kinetic thereby reducing the effects of hemolysis, icterus and lipemia.

24.6 Results

An on-board Quality Control program serves as a real-time performance monitor designed to be used as a result evaluation tool. All QC results are monitored by laboratory established evaluation rules and an audiovisual alarm will alert the Operator to out-of-control performance so that corrective action may be taken immediately. All QC data points are logged by date and time performed. Any QC violations are logged. Although QC data points may be edited to avoid skewing of statistics by out-of-range results, points cannot be deleted thereby assuring a factual representation of test performance. A security system is available that will provide a QC audit trail providing such information as the Operator performing the testing and the Operator editing or commenting on QC results. Multirule charts show at a glance whether controls are within established limits.

Duplicate results are checked to assure that the established variance is not exceeded. All duplicate values that do not agree within the set variance limits are automatically repeated. After repeating, duplicates that do not agree are automatically flagged.

When calculating results from a dilution calibration curve, all results exceeding the curve limits are automatically repeated at a greater or lesser dilution as appropriate.

The instrument automatically recognizes and flags many error conditions such as barcode discrepancy errors, duplicate errors, calculation errors, no coagulation and insufficient sample. No result is printed for any sample flagged with an error condition.

Results cannot be edited. Error coding results for unusual sample conditions such as hemolysis, icterus and lipemia are available.

25 TROUBLESHOOTING.....25-1
25.1 NON-FATAL ERRORS..... 25-1
25.2 FATAL ERRORS 25-1
25.3 GENERAL TROUBLESHOOTING 25-3

The AMAX 200 is designed to self-diagnose and has many systems operational checks that continuously monitor the operation of the system. When the system detects an out-of-range condition, an audible alert immediately sounds and a message describing the error source is displayed on the monitor. The operational status of the instrument is always shown by a series of signal lights. When an error condition has occurred, the signal lights may be observed from a distance and, together with the audible alert, serve to notify an operator temporarily out of the immediate area that a condition exists that requires attention.

25.1 Non-Fatal Errors

When a condition is detected that does not jeopardize the quality of tests currently in progress but if not attended to within a short time period could affect future testing, a message will be displayed indicating the elapsed time since the error occurred. The operator has 5 minutes (300 seconds) to either correct the condition or to interrupt processing. If the condition is not corrected within 5 minutes, the instrument will automatically stop processing. Confirmation for continuation of testing is required.

```
Continue? (Y/N)      35 Sec.
```

Press **<Alt-F2>** to silence the alarm. Correct the irregular condition and press **<y><Enter>** to continue processing. If correction cannot be accomplished within 5 minutes, press **<n><Enter>** to stop processing. The tests currently in process will be completed. New testing will not begin. If no answer is given within the allotted time frame, processing will be automatically interrupted.

The error condition will be printed in the real-time printout before each ensuing result.

Conditions falling under this class of errors are:

- Fresh water supply low;
- Liquid waste container full;
- Too few cuvette boxes; and,
- Cuvette cassette waste chute full.

The instrument also allows itself 5 minutes to correct minor internal irregularities. The warning will automatically cancel if adjustment to specifications occurs within 5 minutes.

25.2 Fatal Errors

If a condition is detected that could affect the quality of test results, the audible alert sounds and processing is automatically and immediately aborted.

```
ABORT Run aborted

                              press any key
```

Press **<Alt-F2>** to silence the alarm. Press **<any key>** to clear the screen.

Take corrective action as required. Call Sigma Diagnostics Technical Service (800-325-0250) for assistance in resolving problems.

If an unresolvable internal mechanical or software system error occurs, processing is immediately aborted. A screen describing the problem is displayed. Directions for proceeding are also suggested.

> Error Robot <133> Hdw. error. Switch system off and on again. Carry out PC reset.

Before switching the instrument off, record the module causing the error and the error number code. If the condition does not resolve itself, this information will be of assistance in resolving the condition.

> **WARNING!**
> Do not switch OFF and back ON rapidly. Wait 10-15 seconds after switching OFF before switching back ON again.

While the instrument is OFF, if the error involves the robot, dilutor, sample/reagent tray, or cuvette modules, look at these areas to see if there is a visible cause for the error. Take appropriate corrective action. Some of the possible causes are:

- **Robot**
  A. Obstruction within area is restricting movement. Remove obstruction.
  B. Lid of storage area not positioned correctly. Reposition so that the notch straddles the guide.
- **Dilutor**
  A. Obstruction under dilutor plunger is restricting downward movement. Remove obstruction.
- **Cuvette**
  A. Cuvette box disposal area full. Transport mechanism is unable to dispose of last cuvette box. Clear disposal area of all discarded cuvette boxes and/or plastic strips.
  B. Cuvette box inserted with arrows pointing out of chute. Reposition with arrows pointing into the chute.
  C. Cuvette box inserted upside down. Turn box over so that the arrows are on top and pointing into the chute.
  D. Cuvette in the first row of cuvettes is not aligned correctly and the transfer mechanism is unable to deliver it into the incubation rail. Either align correctly or remove the offending cuvette. If this error occurs repeatedly with this cuvette box, remove and discard box.
  E. Cuvette box transport mechanism is unable to engage the first cuvette box. Pull the mechanism up and position down correctly behind the plastic strip behind the last row of cuvettes. If this error occurs repeatedly, call Sigma Diagnostics Technical Service (800-325-0250).

F. Plastic strip behind box is not moving freely. Transport mechanism is unable to advance a new row of cuvettes. Press on strip to allow freedom of movement. If this error occurs repeatedly with this cuvette box, remove and discard.

- **Reagent/Sample Tray**
  A. Trays are not positioned correctly. Alignment holes on both trays must be positioned over the corresponding guide pins. Position correctly.
  B. Obstruction within storage area is interfering with movement. Remove obstructing object.

After correcting any observable problem, switch the instrument back ON. During power ON, the system automatically goes through a system reset. This often corrects what appears to be an unresolvable problem.

As soon as the operating program restarts, any cuvettes that were in process in the incubation rail will be automatically removed and discarded. If the problem was in the cuvette module observe this process to ascertain that the condition has been corrected.

Proper functioning of the cuvette module may also be checked by using the "Transfer cups" command. **<Service><Transfer cups>**. Press **<Enter><Enter>** and type in the **number** (1-400) of cups to transfer (2-3 is usually an adequate function check if the problem occurred in the middle of a row but may require more than 10 if the problem occurred when a new cuvette row was delivered to the transfer row). Transfer will stop automatically when only one box is left.

If any error occurs repeatedly, call Sigma Diagnostics Technical Service (1-800-325-0250).

WARNING!
Internal instrument repair work should only be performed by authorized service personnel.

25.3 General Troubleshooting

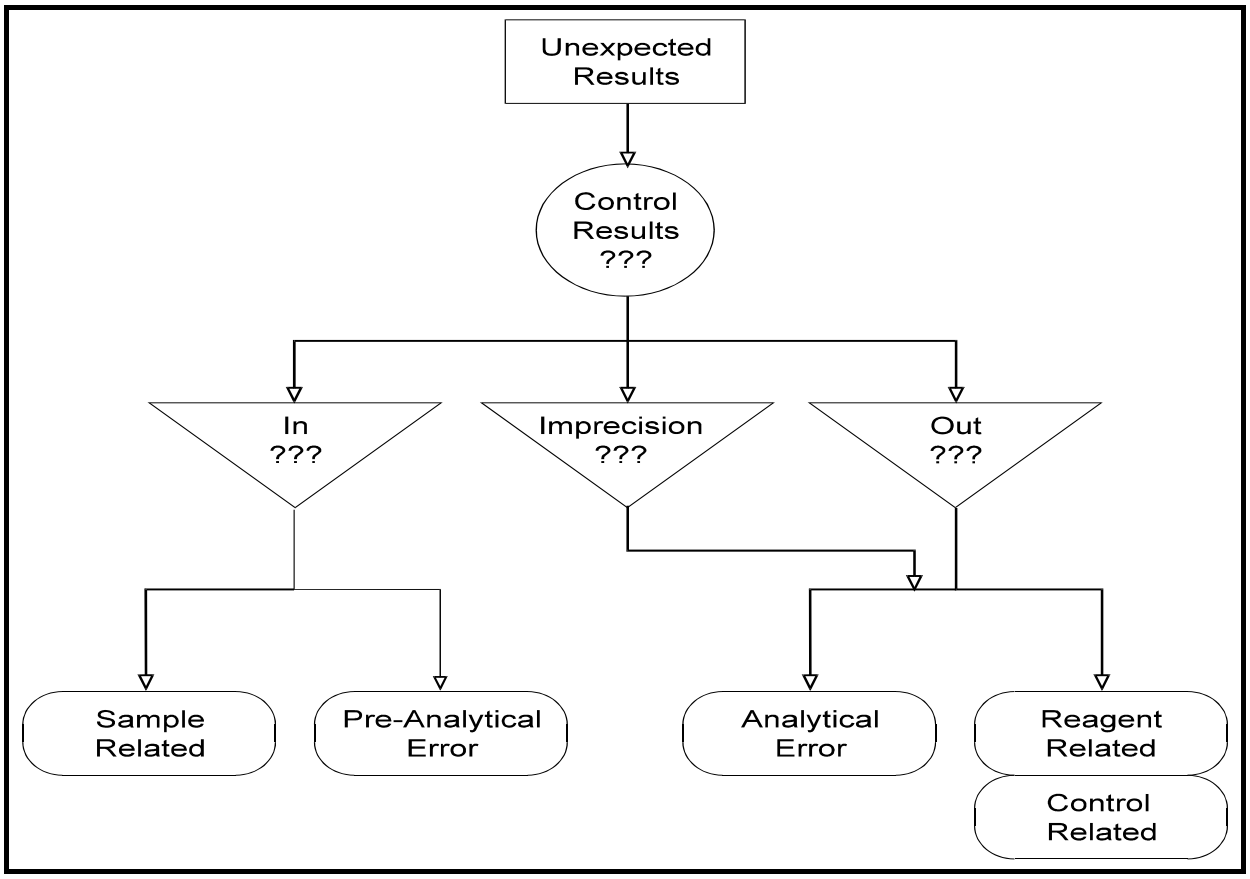
The majority of the time when unexpected results are obtained during testing, the cause will not be an internal system error. Unexpected results may be caused by any of the following:

- Sample related error
- Pre-analytical error
- Analytical error
- Reagent related error

The first troubleshooting step is always to look at the control results. If the controls are within established acceptable limits, the areas to look at closely are those related to the sample and preanalytical conditions. Something prior to the actual analysis is causing the unexpected results. If the controls are outside established acceptable limits, the analytical process including reagent, control, operator and instrument performance is in question.

If sample and pre-analytical errors have been excluded, use the "Channel statistics" (**<Ctrl-F1>**) monitor to determine if all or most errors are channel oriented. The combined use of the "AMAX AMAX=USEPOOL" DOS parameter and channel statistics can be a very effective way to isolate a measuring channel problem (NCs, short times or imprecision).

12.3
12.4



Controls within limits Unexpected results on isolated patient(s)		
Origin	**Possible Cause**	**Corrective Action/Explanation**
Sample related	Pathological clinical condition of patient	DIC or other condition resulting in the presence of *in vivo* activated factors. Results may be supernormal and erratic. Re-run sample using the optical measurement mode with Graphics Mode on. Observe reaction. In normal samples, the reported time will be close to the maximum slope time. In samples containing activated factors, the reported time will be much shorter than the maximum slope time.
		Low fibrinogen will greatly prolong the results of many coagulation tests.
		Many clinical conditions cause depletion of essential factors resulting in greatly prolonged coagulation tests.

Controls within limits Unexpected results on isolated patient(s)		
Origin	**Possible Cause**	**Corrective Action/Explanation**
Sample related (Continued)	Pathological clinical condition of patient (Continued)	Presence of a circulating specific or non-specific inhibitor. The most commonly occurring non-specific inhibitors are heparin, Lupus anticoagulant, FDPs and paraproteins.
		Any clinical condition of patient resulting in icterus, lipemia or *in vivo* hemolysis. Icterus is indicative of liver disease that often results in decreased production of coagulation factors resulting in prolonged coagulation times. Mechanical methods are less prone to interference from mild to moderate lipemia and hemolysis. Because of the dilution displacement effect of excessive levels of lipoproteins, extreme lipemia will affect the results of both mechanical and optical tests. Times will be increased proportional to the level of lipemia.
	Administration of heparin or antithrombolytic agents	Either or both may have been administered in the ER before general admission or transfer to another facility.
	High or low hematocrit	Failure to correct citrate volume for patients with high (<55%) or low (>21%) hematocrit. The ratio of anticoagulant to blood is inappropriate. Redraw with correct volume of anticoagulant.
	Aspiration below RBC/plasma interface	High hematocrit resulting in aspiration from below the RBC/plasma interface. Transfer plasma to a tube and retest.
		Plasma depleted in primary tube. Level sense not set appropriately to avoid aspiration below RBC/plasma interface. Call Sigma Diagnostics Technical Service for assistance in setting the sample depth level.
	Short draw	The ratio of anticoagulant to blood is critical. Redraw patient.
	Compromised sample integrity	Check for micro clots and hemolysis. Redraw patient.
Pre-Analytical error	Delay in transporting or processing	Many coagulation factors are unstable. Store PTs no longer than 24 hours at room temperature (18-26°C) or refrigerated (2-8°C). Store APTTs no longer than 4 hours at room temperature (18-26°C) or refrigerated (2-8°C). Centrifuge APTTs suspected of containing heparin (UFH) within 1 hour of collection and test within 4 hours.
	Cryoprecipitation	If using frozen samples, inappropriate thawing results in cryoprecipitation of fibrinogen and other factors. Quick thaw at 37°C. Store on ice until processing can begin (maximum time prior to testing = 2 hours). Avoid heating at 37°C for more than 5 minutes.

Controls within limits Unexpected results on multiple patients		
Origin	**Possible Cause**	**Corrective Action/Explanation**
Pre-Analytical error	Incorrect volume, anticoagulant type (e.g., EDTA, heparin), concentration or lack of anticoagulant	Use anticoagulant as recommended by the reagent manufacturer.
	Inadequate or too vigorous mixing of specimen with anticoagulant	Invert gently to mix well without mechanical trauma.
	Contaminated collection or storage tube	Try another lot of vacuum tubes or another manufacturer. Use only clean, dry tubes with a non-wettable surface for storage. Re-washing is not advised.
	Inappropriate centrifugation	Centrifuge whole blood samples immediately. Centrifuge at the correct rcf for the correct time interval. Reliable performance of many coagulation procedures is dependent on having platelet-poor plasma. Centrifuge APTTs suspected of containing heparin within 1 hour of collection.
	Contact with glass	Contact with glass may cause premature activation. Transfer plasma to plastic storage tubes using plastic transfer pipettes.
Controls outside of established limits		
Control related	Deteriorated or contaminated control material	Prepare fresh controls.
	Incorrectly reconstituted control material(s)	Reconstitute according to the manufacturer's instructions. Use only the recommended diluent to reconstitute.
	New or different lot number of control material	Check to assure that lot number used is the same as that used for establishing the limits.
Reagent related	Continued repeated addition of new reagent to old reagent	Reconstitute or open a new bottle of reagent. Continued repeated addition of new reagent to old reagent may lead to changes in the reagent composition which many change its reactivity. It may also lead to microbial contamination. Reagent containers that are reused should be thoroughly decontaminated with 10% bleach, rinsed thoroughly in tap water, rinsed in DI water and dried prior to reuse.
	Contaminated reagent caused by the inadvertent combination of two reagents	Reconstitute or open a new bottle of reagent. Check reagent layout for proper positioning prior to adding reagent to reagent already on-board. Always add reagent using the Halt procedure. The tray moves very quickly and reagent may be inadvertently poured into other open containers. Replace all affected reagent containers.

Controls outside of established limits		
Origin	**Possible Cause**	**Corrective Action/Explanation**
Reagent related (Continued)	Stir bar contamination	Contaminated reagent caused by a contaminated stir bar. Stir bars must be decontaminated regularly. Care must be taken not to inadvertently switch stir bars from one reagent to another when adding replenishing reagents.
	Incorrectly reconstituted reagent	Reconstitution with incorrect diluent volume or incorrect diluent. Follow manufacturer's instructions.
	Wrong reagent being used	Check to assure that the right reagent is in the designated reagent layout position.
	New lot number of reagent	New lot number of reagent with a slightly different reactivity. Lot-to-lot variation in reagent reactivity is not unusual. Re-verify reference range. Prepare new calibration curves as appropriate.
	Shipping or storage effects	Reagent defective due to mishandling in shipping or storage. Is this the first use of reagent in this shipment? Try reagent from a different shipment. Is the temperature of the storage area appropriate? Adjust storage area temperature as appropriate.
	Reagent deteriorated	Prepare new reagent. Do not use unreconstituted reagent that is beyond the expiration date or reconstituted reagent that is beyond the stated reconstituted stability time.
Analytical error	Wrong reagent being used	Check Test Parameters Procedure Section to assure that the correct reagent is programmed. Assure that positioning in reagent tray matches reagent layout assignment.
	Enzyclean not being used	Enzyclean removes protein build-up and minimizes cross-contamination. Assure that Enzyclean container is present and contains Enzyclean.
	Incorrect volume of reagent being used	Check Test Parameters Procedure Section to assure correct programming of volumes. Follow reagent manufacturer's application for the AMAX 200.
	Incorrect volume of sample being used	Check Test Parameters Procedure Section to assure correct programming of volumes. Follow reagent manufacturer's application for the AMAX 200.
	Incorrect sample dilution being used	Check Test Parameters Calibration Section to assure correct programming of the dilution ratio. Follow reagent manufacturer's application for the AMAX 200.
	Incorrect incubation time being used	Check Test Parameters Procedure Section to assure correct incubation times. Follow reagent manufacturer's application for the AMAX 200.

Controls outside of established limits		
Origin	**Possible Cause**	**Corrective Action/Explanation**
	Incorrect testing sequence	Check Test Parameters Procedure Section to assure correct sequencing. Follow reagent manufacturer's application for the AMAX 200.
	Inappropriate delay, impulse or other time settings	Check Test Parameters Calibration Section to assure appropriate timing. Follow manufacturer's application for the AMAX 200
Within-run imprecision. Duplicate errors. Controls may be in or out of established limit		
Analytical error	Failure to add stir bar to particulate reagents	Add stir bar.
	Enzyclean not being used	Enzyclean removes protein build-up and minimizes cross-contamination. Assure that Enzyclean container is present and contains Enzyclean.
	Incorrect reagent tray positioning of stirred reagents	Reagents containing stir bars must be placed in position 9, 17 or 18. Reassign reagent layout(s) as appropriate.
	Incorrect stir bar being used	A stir bar with wings should be used for kaolin-containing reagents.
	Incorrect stir bar speed setting	If too slow there will be inadequate stirring. If too fast there will be excessive foaming, vortex formation or bubble formation that interferes with accurate aspiration. Call Sigma Diagnostics Technical Service for assistance in adjusting the speed.
	Missing ball	Only mechanical tests will be affected. Assure that top of cuvette box is not bowed thereby allowing movement of balls between cuvettes.
	Pipetting imprecision	Check tubing for large bubbles and air gaps. Check top of syringe plunger for residue accumulation or bubbles. Clean or replace as necessary. If using fresh water from a pressurized source, degas prior to installation on the instrument. Always perform a system prime after replenishing the fresh water supply.
	Dirty optical measuring wells	Clean wells and perform photometer calibration procedure. Replace lamp as necessary. Call Sigma Diagnostics Technical Service for assistance in performing photometer calibration.
	Incorrect dispense rate setting	Excessive bubble formation during dispense of sample and/or reagent. Optical measurement mode graphic will show turbulence over a long time span. Adjust individual dispense rate (+n) to decrease dispense rate. If all tests are affected, call Sigma Diagnostics Technical Service for assistance in re-setting the master default dispense rate.

Within-run imprecision. Duplicate errors. Controls may be in or out of established limit		
Origin	**Possible Cause**	**Corrective Action/Explanation**
Analytical error (Continued)		Inadequate mixing of sample with reagent(s). Adjust individual dispense rate (-n) to increase dispense rate. If all tests are affected, call Sigma Diagnostics Technical Service for assistance in re-setting the master default dispense rate.
High total imprecision (run-to-run variability)		
Control related	Deteriorated controls	Use within manufacturer's stated reconstitution limits. Prepare fresh control materials.
	Inconsistent or inaccurate reconstitution of control material(s)	Reconstitute as directed by the manufacturer.
Reagent related	Inconsistent or inaccurate reconstitution of reagent.	Follow reagent manufacturer's instructions for reagent preparation in the application for the AMAX 200.
	Reagent concentration caused by evaporation	Reagents should be capped when not in active use. Calcium chloride is particularly sensitive to evaporative changes.
Analytical error	Enzyclean not being used	Enzyclean removes protein build-up and minimizes cross-contamination. Assure that Enzyclean container is present and contains Enzyclean.
	Failure to consistently add stir bars to particulate reagents	Add stir bar(s).
	Incorrect reagent tray positioning of stirred reagents	Reagents containing stir bars must be placed in position 9, 17 or 18. Reassign reagent layout(s) as appropriate.
	Incorrect stir bar being used	A stir bar with wings should be used for kaolin-containing reagents.
	Incorrect stir bar speed setting	If too slow, there will be inadequate stirring. If too fast, there will be excessive foaming or bubble formation that interferes with accurate aspiration. Call Sigma Diagnostics Technical Service for assistance in adjusting the speed.
	Pipetting imprecision	Fresh water out-gassing. If using fresh water from a pressurized source, degas prior to installation on the instrument. Always perform a system prime after replenishing the fresh water supply.
		Check tubing for large bubbles and air gaps. Check top of syringe plunger for residue accumulation or bubbles. Clean or replace as necessary.
		Check tubing for leaks. Replace as necessary.

High total imprecision (run-to-run variability)		
Origin	**Possible Cause**	**Corrective Action/Explanation**
Analytical error (Continued)	Incorrect predilution level settings	Predilution mode only. Imprecision caused by incorrect predilution level settings. Cuvette height, dispensing height and aspiration height must all be set correctly. Call Sigma Diagnostics Technical Service for assistance in adjusting the predilution levels.
	Dirty optical measuring wells	Clean wells and perform photometer calibration procedure. Replace lamp as necessary. Call Sigma Diagnostics Technical Service for assistance in performing photometer calibration.
	Incorrect dispense rate setting	Excessive bubble formation during dispense of sample and/or reagent. Optical measurement mode graphic will show turbulence over a long time span. Adjust individual dispense rate (+n) to decrease dispense rate. If all tests are affected, call Sigma Diagnostics Technical Service for assistance in re-setting the master default dispense rate.
		Inadequate mixing of sample with reagent(s). Adjust individual dispense rate (-n) to increase dispense rate. If all tests are affected, call Sigma Diagnostics Technical Service for assistance in re-setting the master default dispense rate.
	System contamination	A clean well-maintained system always gives the best performance. Disinfect system. Clean and disinfect fresh water container regularly. Rinse thoroughly before reinstalling on instrument. Perform maintenance procedures as scheduled.
No coagulation		
Sample related	Low fibrinogen level	A deficiency of fibrinogen will greatly prolong the results of many coagulation tests.
	High heparin dosage	Heparin inhibits clot formation and with high dosage results in the formation of a clot of poor quality. Such samples may give erratic results. Heparin containing samples are more susceptible to deterioration than normal samples.
Analytical error	Missing ball	Only mechanical tests will be affected. Assure that cuvette box top is not bowed thereby allowing movement of balls from one cuvette to another.
	Inappropriate Max time setting	Check Max time and Max time 2 settings. Increase as appropriate. <System><Parameters><Test Parameters><Calibration>
No coagulation Clot formed but not detected		
Sample related	Clot formed prior to delay time setting	Check Test Parameters Calibration Section to assure correct setting. Re-run sample in optical measurement mode with Graphics Mode on. Observe reaction.

Origin	Possible Cause	Corrective Action/Explanation
No coagulation Clot formed but not detected		
	Excessively high fibrinogen	Clauss fibrinogens. Dilute sample 1:2 or more with recommended buffer and repeat. Multiply result by the dilution factor to compensate for dilution.
Reagent related	Incorrect reagent being used	Check positioning of reagents in reagent tray.
Analytical error	Malfunctioning measurement channel	Catch cuvettes to observe for patency of clot formation. Use tweezers to remove cuvettes from mechanical wells. Observe pattern of results. Identify offending channel and lock out of service. Use "Channel statistics" (<Ctrl-F1>) to help determine channel failure. Call Sigma Technical Service for assistance.
	Missing ball	Only mechanical tests will be affected. Care should be taken not to invert the cuvette boxes once the protective plastic shield has been removed.
	Inappropriate Max time setting	Check Max time and Max time 2 settings. Increase as appropriate. <System><Parameters><Test Parameters><Calibration>
Incorrect reagent level monitoring		
Analytical error	Incorrect level settings	Highest accuracy in setting levels is obtained when all reagent containers within a reagent ring are the same size. Call Sigma Diagnostics Technical Service for assistance in setting levels appropriately.
No Stat positions available		
Analytical error	No positions assigned in reagent layout assigned to currently active Test Group	Assign positions (1-8) in reagent layout (<System> <Parameters> <Reagent Layout>)
Unable to access Quick-Start or Tray Menus		
Analytical error	Positive-ID active	Switch Option setting to position oriented. (<System><Options>)
No QC data stored		
Analytical error	Request not prefaced appropriately	Requisition as QC Code defined in Control Definition plus sequence identifier. Valid sequence identifiers are: 00-99, 0A through Z9, A0 through Z9, AA through ZZ.
	Control not defined	<QC><Q.C.Setup><Controls>
	QC File not activated	<QC><QC Files><Create>
QC Zoom Chart won't Open		
Not an error	Insufficient number of points	Must be at least 3 valid points to open the Zoom Chart. Run more points.

Duplicate QC Charts		
Origin	**Possible Cause**	**Corrective Action/Explanation**
Not an error	Duplicate Test Codes	Test Codes must be unique. (<System><Parameters><Tests><Description>).
No distribution data stored		
Analytical error	Distribution data reduction type set to “N”	Test parameters, Statistics section. Program data type as “T”, “R”, or “C” as appropriate(<System> <Parameters> <Tests> <Statistics>)
	Inappropriate collection range	Set range appropriately. Only results falling within the designated range are collected.(<System> <Parameters> <Tests> <QC/Statistics>)

26 INSTALLATION 26-1
26.1 INSTALLATION 26-1
26.2 LOCATION REQUIREMENTS 26-1
26.3 ELECTRICAL REQUIREMENTS AND PRECAUTIONS 26-1
26.4 REMOVAL OF SHIPPING SAFETY CLAMPS 26-2
26.5 FRESH WATER AND DRAIN CONNECTIONS 26-2
26.6 POWER ON 26-2

26.1 Installation

A Sigma-Amelung authorized representative is responsible for unpacking, installing and initial setup of the AMAX 200.

26.2 Location Requirements

1. Locate the AMAX 200 on a level, stable, vibration and dust free work surface that is deep enough to allow air circulation to the back of the instrument. To allow for adequate instrument cooling, there must be at least four (4) inches between the back of the instrument and any wall. It should not be positioned next to centrifuges or other equipment that many cause vibration.

   Minimum Space Requirements (includes AMAX 200 and peripheral equipment):

   Width: 6 feet (1.6 m)
   Depth: 32 inches (80 cm)

2. Locate the AMAX 200 in an area of low humidity and little temperature fluctuation. It should not be positioned in an area directly below ventilating ducts which produce strong air currents.
3. Locate the AMAX 200 in an area not illuminated by direct sunlight.
4. The instrument must be located no further than 5 feet (1.5 m) from an electrical outlet. A total of four (4) outlets will be required. The instrument should not be operated from an extension cord that does not employ protective grounding. The electrical outlet line should not be shared with large power-consuming devices which are frequently turned on and off (e.g. centrifuges, air conditioners or refrigerators). When these type of devices power on and off, there may be enough voltage drop on the line to interfere with proper functioning of the instrument.

26.3 Electrical Requirements and Precautions

1. The AMAX 200 is factory equipped with a three-pronged grounding plug designed to be connected with a matching three-pronged receptacle. Under no circumstances should it be connected to an ungrounded two-pronged plug. This procedure is in accordance with the National Electrical Code and other applicable ordinances for this type of installation.
2. Do NOT use an extension cord not equipped to provide protective grounding.
3. Prior to connecting to the electrical outlet, check to ensure that the operating voltage (90-132 V/60 Hz or 180-265 V/50Hz) corresponds to the line voltage.
4. It is recommended that any repair work other than routine maintenance and minor adjustments be performed by a Sigma-Amelung or by a Sigma-Amelung authorized representative familiar with the hazards involved.
5. If safe operation of the AMAX 200 is no longer possible, the instrument must be taken out of service.

26.4 Removal of Shipping Safety Clamps

WARNING!
Shipping safety clamps must be removed from the drive belt and probe prior to system activation.

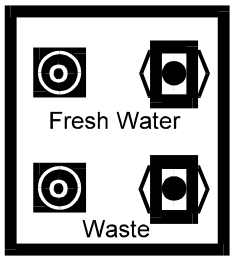
WARNING!
Do not discard the safety clamps. The safety clamps must be reinstalled in the event of future transport.

26.5 Fresh Water and Drain Connections

Fresh water for probe rinsing and washing is supplied from a 21 L container. Fill the fresh water container to the "Max. Level" line with deionized water. Optimum performance will be obtained if the water is allowed to degas prior to installing on the instrument. Degassing is most easily accomplished by allowing the filled container to sit for 8-12 hours prior to installing on the instrument.

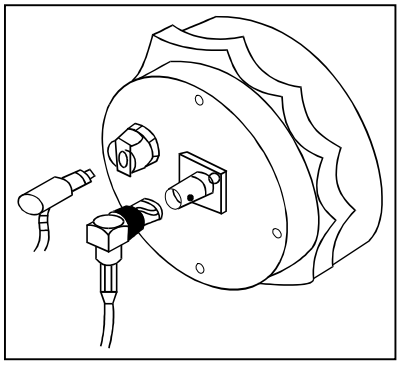
If a base cabinet is being utilized, feed both fresh water and waste tubing harnesses through the hole in the upper left back of the cabinet.

Connect the fresh water tubing and float sensor to the reservoir tank inlets located on the left rear side (when facing the instrument front) of the instrument. The fresh water connections are the top set of connectors.



Connect the waste tubing and float sensor to the waste tank inlets located just below the fresh water inlets.

Guide the sensors and tubes into each container. Tighten the caps onto their respective containers. Care should be taken to turn only the ridged cap and not the area that has the tubing attachments.



The containers can be positioned either beside or below the instrument. If a base cabinet is being utilized, the containers are designed to fit laying on the side in the left-hand side of the cabinet next to the cuvette disposal bin. The containers should be positioned so that the container opening is at the top.

26.8 Power ON

WARNING!
Assure that the shipping safety clamps have been removed.

26.5

Assure that the lid over the Reagent/Sample well is on and correctly positioned. There is a magnet on the bottom right side of the lid notch that must be aligned over the sensor located on the top of the instrument. The lid must be level with the top of the instrument.

Power up the AMAX 200 by pressing the power supply switch from OFF to ON. The switch is located on the lower back corner of the right side of the instrument. The switch lights up green when power to the instrument is ON.

WARNING!
Do not switch OFF and ON rapidly. Wait 10-15 seconds after switching OFF before switching ON.

At power ON, the robot arm and the Reagent/Sample Trays (if positioned in the well) move to the home position.

The Main Menu of the AMAX Operating Program will be displayed on the monitor screen.

Initially, all temperature indicators will be flashing red. After 20-30 minutes, the system reaches operating temperature. As each temperature regulated module reaches temperature, the indicator area for that temperature will stop flashing red.

Refer to appropriate sections in this manual for instructions on how to operate the AMAX 200.

27 INTERFACE SPECIFICATIONS 27-1
27.1 MODES 27-1
27.2 BI-DIRECTIONAL INTERFACE DESCRIPTION 27-1
27.3 PROTOCOL 27-3
27.3.1 MASTER to SLAVE 27-3
27.3.2 SLAVE to MASTER 27-4
27.4 COMMAND CHARACTERS AND SYMBOLS 27-5
27.5 TIMEOUT 27-5
27.6 REPEAT AFTER <NACK> 27-5
27.7 EXAMPLES (AMAX AS MASTER) 27-6
27.8 EXAMPLE OF HEADER AND TEST ORDER 27-10

27.1 Modes

1. Real-Time

   Options Setting: **<System><Options><Positive Id><On-Line: Real-Time>**
   Other option settings user determined.

   Host Parameter Communication Mode Setting: **<System><Host Par.><Master>**

2. Batch

   Options Setting: **<System><Options><Positive Id><On-Line: Batch>**
   Other option settings user determined.

   Host Parameter Communication Mode Setting: **<System><Host Par.><Master or Slave>**

   Operator initiated data transmission from host to AMAX: **<Patients><Import>**
   Operator initiated data transmission from AMAX to Host: **<Patients><Export>**

27.2 Bi-Directional Interface Description

1. **Data Sets.** All data sets are type SDF (Space Defined):
2. **Header** (Length 16 characters)(Batch and Real-Time):

FIELD	Data type	Justified	Char. Number	Note
RECTYPE	TEXT	left	1	"H"
WSID	TEXT	left	5	instrument ID: "AMAX1"
LDATE	TEXT	left	10	Date of the list

3. **Identification** (Length 21 or 121 characters)(Batch and Real-Time Modes)

FIELD	Data type	Justified	Char. Number	Note
RECTYPE	TEXT	left	1	"I"
ID	TEXT	left	20	ID-Code
NAME	TEXT	left	40	name, first and last
DEPT	TEXT	left	20	Location
NOTE	TEXT	left	40	Note

4. **Result/Request** (Length 29 or 45 characters) (Batch and Real-Time Modes)

FIELD	Data type	Justified	Char. Number	Note
RECTYPE	TEXT	left	1	"D"
ID	TEXT	left	20	Sample ID
REQ	TEXT	left	8	Test Code
RESULT1	FLOAT	right	5	Result 1*
RESULT2	FLOAT	right	5	Result 2*
RESULT3	FLOAT	right	5	Result 3*
RESALPHA	TEXT	left	20	Blank (Not Used)
ECODE	TEXT	left	1	Error code *

*: Result transmission order is determined by Data Reduction setting in Test Parameters.

5. **ID-Query** (Length 26 characters)(Real-Time Mode):

FIELD	Data type	Justified	Char. Number	Note
RECTYPE	TEXT	left	1	"Q"
WSID	TEXT	left	5	Instrument ID: "AMAX1"
ID	TEXT	left	20	Sample-ID

6. **Result** (continuous) (Length 50 characters)(Real-Time Mode):

Field	type	Justified	Char. Number	Note
RECTYPE	TEXT	left	1	"R"
WSID	TEXT	left	5	Instrument ID "AMAX1"
ID	TEXT	left	20	Sample ID
REQ	TEXT	left	8	Test Code
RESULT1	FLOAT	right	5	Result 1
RESULT2	FLOAT	right	5	Result 2
RESULT3	FLOAT	right	5	Result 3
RESALPHA	TEXT	left	20	Blank (Not Used)
ECODE	TEXT	left	1	Error code

*: Result transmission order is determined by Data Reduction setting in Test Parameters.

27.3 Protocol

The following communication protocol is used for both data transmission directions. According to the configuration the AMAX 200 assumes the function MASTER or SLAVE:

27.3.1 MASTER to SLAVE

MASTER	SLAVE	Note
<DLE>		Start communication
<TC>	<ACK> <TC>	ready
<STX> Text ("H.....") <ETX> <CHKS> <TC>		Header is transmitted
   (Record is sent again)	<ACK> <TC> or <NACK> <TC>	Data checked and OK Error
<STX> Text ("I.....") <ETX> <CHKS> <TC>		Sample -ID record sent
   (Record is sent again)	<ACK> <TC> or <NACK> <TC>	Data checked and OK error
<STX> Text ("D.....") <ETX> <CHKS> <TC>		Test request record sent
   (Record is sent again)	<ACK> <TC> or <NACK> <TC>	Data checked and OK error
" "		
<EOT> <TC		End of transmission
	<ENQ> <TC>	start of communication
<EOT> <TC>		no data available

27.3.2 SLAVE to MASTER

SLAVE	MASTER	Note
<STX> Text ("H.....") <ETX> <CHKS> <TC>		Header is sent
   (Record is sent again)	<ACK> <TC> or <NACK> <TC>	Data checked and OK error
	<ENQ> <TC>	request next data string
<STX> Text ("I.....") <ETX> <CHKS> <TC>		Sample-ID record
   (Record is sent again)	<ACK> <TC> or <NACK> <TC>	Data checked and OK error
	<ENQ> <TC>	request next data string
<STX> Text ("D.....") <ETX> <CHKS> <TC>		Test request record sent
   (Record is sent again)	<ACK> <TC> or <NACK> <TC>	Data checked and OK Error
	<ENQ> <TC>	Request data string
<EOT> <TC		No more data available

27.4 Command Characters and Symbols

<DLE>	ASCII code 10h
<STX>	ASCII code 02h
<ETX>	ASCII code 03h
<ACK>	ASCII code 06h
<NACK>	ASCII code 15h
<EOT>	ASCII code 04h
<ENQ>	ASCII code 05h
<CHKS>	Checksum (2 ASCII characters). The checksum is calculated summing the ASCII codes of all characters between<STX> and <ETX>. The modulo 256 of the sum is converted to its hexadecimal form. If the checksum is longer than one byte, only the lower byte is used for the checksum.
<TC>	Consists of a free programmable command sequence. May be up to two user-definable character strings.

27.5 Timeout

Each data transfer must be acknowledged within 10 sec. Failing to do so will cause the protocol to be aborted. Data transfer must be restarted. The time period 10 sec. is a default parameter. It can be changed by using the DOS parameter HOST=nn in the AMAX.ini where “nn” equals the desired timeout time.

27.6 Repeat after <NACK>

Data strings refused with a <NACK> will be resent up to three (3) times. After resending the third time, the protocol will be aborted.

27.7 Examples (AMAX as MASTER)

1. **Import (download of the requests from LIS to AMAX)(Real-Time)**

```
AMAX:      ENQ TC
LIS:       STX  |H|AMAX1|MM/DD/YYYY
                |1|__5__|____10____|ETX Checksum TC

AMAX:      ACK TC
AMAX:      ENQ TC

LIS:       STX  |I|11111111            |
                |1|_________20_________|
                |NAME, FIRST AND LAST                    |
                |____________________40____________________|
                |LOCATION            |
                |_______20___________|
                |NOTE                                    |
                |____________________40____________________| ETX Checksum TC

AMAX:      ACK TC
AMAX:      ENQ TC

LIS:       STX  |D|11111111            |   PT   |
                |1|_________20_________|___8____||ETX Checksum TC

AMAX:      ACK TC
AMAX:      ENQ TC

LIS:       STX  |D|11111111            |  PTT   |
                |1|________20__________|___8____| ETX Checksum TC

AMAX:      ACK TC
AMAX:      ENQ TC

LIS:       STX  |I|11111112            |
                |1|_______20___________|
                |NAME, FIRST AND LAST                    |
                |____________________40____________________|
                |LOCATION            |
                |_______20___________|
                |COMMENT |
                |____________________40____________________| ETX Checksum TC

AMAX:           ACK TC
AMAX:           ENQ TC

LIS:            STX  |D|11111112            |PT      |ETX Checksum TC
                |1|________20__________|___8____|

AMAX:           ACK TC
AMAX:           ENQ TC

LIS:            STX  |D|11111112            |FIB     |
                |1|________20__________|___8____| ETX Checksum TC

AMAX:           ACK TC
AMAX:           ENQ TC
LIS:            EOT TC
```

2. **Import (upload of results from AMAX to LIS)(Real-Time Mode, continuous transmission)**

```
AMAX:      DLE TC
LIS:       ACK TC

AMAX:      STX  |R|AMAX1|11111111            |   PT   |
                |1|__5__|________20__________|___8____|

                | 12.3| 95.4| 1.03|                    | |
                |__5__|__5__|__5__|_________20_________|1| ETX Checksum TC

LIS:       ACK TC

AMAX:      STX|R|AMAX1|11111112            |PT      |
                |_|__5__|________20__________|___8____|

                | 14.0| 74.4| 1.10|                    | |
                |__5__|__5__|__5__|_________20_________|_| ETX Checksum TC

LIS:       ACK TC
AMAX:      EOT TC
```

1. **Export (upload from AMAX to LIS)(Batch Mode)**

```
AMAX:      DLE TC
LIS:       DCK TC

AMAX:      STX  |H|AMAX1|MM/DD/YYYY|ETX Checksum TC
                |_|__5__|____10____|

LIS:       ACK TC

AMAX:      STX  |I|11111111            |
                |1|_______20___________|
                |INSTANCE NAME |
                |_____________________40_____________________|
                |LOCATION           |
                |_______20___________|
                | NOTE                                  |ETX Checksum TC
                |_____________________40_____________________|

LIS:       ACK TC

AMAX:      STX  |D|11111111            |PT      |
                |1|________20__________|___8____|
                | 12.3| 95.4| 1.03|                    | |ETX Checksum TC
                |__5__|__5__|__5__|_________20_________|1|

LIS:       ACK TC

AMAX:      STX  |D|11111111            |PTT     |
                |_|________20__________|___8____|
                | 32.4|     |     |                    | |ETX Checksum TC
                |__5__|__5__|__5__|________20__________|1|

LIS:       ACK TC

AMAX:      STX  |I|11111112            |
                |1|_______20___________|
                |NAME, FIRST AND LAST |
                |_____________________40_____________________|
                |LOCATION           |
                |_______20___________|
                |COMMENT                                |ETX Checksum TC
                |_____________________40_____________________|

LIS:       ACK TC

AMAX:      STX  |D|11111112            |PT      |
                |_|________20__________|___8____|
                | 14.0| 74.4| 1.10|                    | |ETX Checksum TC
                |__5__|__5__|__5__|_________20_________|1|

LIS:       ACK TC

AMAX:      EOT TC
```

2. **ID Query (Real Time)**

```
AMAX:      DLE TC

LIS:       ACK TC

AMAX:      STX  |Q|AMAX1|11111111            |ETX Checksum TC
                |_|__5__|________20__________|

LIS:       ACK TC

AMAX:      EOT TC

LIS answers with patient data:

AMAX:      ENQ TC

LIS:       STX  |H|AMAX1|MM/DD/YYYY|ETX  Checksum TC
                |_|__5__|____10____|

AMAX:      ACK TC

AMAX:      ENQ TC

LIS:       STX  |I|11111111            |
                |_|_______20___________|
                |NAME, FIRST and LAST                    |
                |_____________________40_________________|
                |LOCATION             |
                |_______20____________|
                |NOTE                                    |ETX  Checksum TC
                |_____________________40_________________|

AMAX:      ACK TC
AMAX:      ENQ TC

LIS:       STX  |D|11111111            |PT      |ETX Checksum TC
                |_|________20__________|___8____|

AMAX:      ACK TC

AMAX:      ENQ TC

LIS:       STX  |D|11111111            |PTT     |ETX Checksum TC
                |_|________20__________|___8____|

AMAX:      ACK TC

AMAX:      ENQ TC

LIS:       EOT TC
```

Notes:

A. Test types are user programmable up to 8 case sensitive alpha-numeric characters. The way a test is entered must match at the AMAX and the LIS to operate correctly. Example: if PT-M is entered for a Test Code at the AMAX, it must also be entered as PT-M at the LIS for the correct match to be made.

B. Data transmission can be alpha-numeric in both directions (AMAX to LIS and LIS to AMAX).

27.8 Example of Header and Test Order

No.	Header		Test Order	
	Code	ASCII	Code	ASCII
0	<STX>	02	<STX>	02
1	H	48	D	44
2	A	41	4	34
3	M	4D	7	37
4	A	41	1	31
5	X	58	1	31
6	1	31	<SPC>	20
7	6	36	<SPC>	20
8	/	2F	<SPC>	20
9	0	30	<SPC>	20
10	3	33	<SPC>	20
11	/	2F	<SPC>	20
12	1	31	<SPC>	20
13	9	39	<SPC>	20
14	9	39	<SPC>	20
15	9	39	<SPC>	20
16	<ETX>	03	<SPC>	20
17	<CHKS>6	36	<SPC>	20
18	<CHKS>D	44	<SPC>	20
19	<CR>	0D	<SPC>	20
20	<LF>	0A	<SPC>	20
21			<SPC>	20
22			P	51
23			T	54
24			<SPC>	20
25			<SPC>	20
26			<SPC>	20
27			<SPC>	20
28			<SPC>	20
29			<SPC>	20
30			<ETX>	03
31			<CHKS>7	37
32			<CHKS>6	36
33			<CR>	0D
34			<LF>	0A

Abbreviated Quick-Start Operating Procedure:

		Chapter Reference
1.	Enter Quick-Start: **<Stat Menu><Enter><Quick-Start><Enter>**	**9.1**
2.	Test Group Selection: **<F3><Test groups><Enter><Appropriate Group><Enter>**	**9.3**
3.	Order Tests: **<Type ID><Enter>** and **< → >** to go to **<test to be ordered>** select with **< ✷ > or <+>**. **<F8>** to go to panel list **<panel #><Enter>** to order all tests in the panel. **< / >** backs cursor to the left, **< - >** advances cursor to the right. **<Enter>** advances to the next sample ID. **<Shift-Enter>** or **<Shift ↓>** copies ordered same tests to next sample.	**9.4**
4.	Prepare Reagent Tray: **<F3><Reagent overview><Enter>** to see reagent layout. Check for sufficient amounts either manually or automatically. Remove all lids. Automatic: **<F3><Check reagent><Enter>**. Replenish reagents as necessary.	**9.5**
5.	Check fresh water supply and drain waste. Fill or empty as necessary. Check cuvette boxes supply. Add as necessary.	**9.6**
6.	Start Processing: Position samples appropriately. **<F9>** to start processing. Screen displays order of samples. **<Enter>** to confirm and start run.	**9.7**
7.	Stop Processing: **<F3><Stop><Enter>** for a soft stop; or **<Abort><Enter>** for a hard stop.	**9.8**
8.	Check QC results: **<F1><Q.C. Charts>**	**9.9**
9.	Add New Samples: Go to next open position. Type in ID and order tests. **<F9>** to start processing.	**9.10**
10.	Repeating Tests: With cursor over test to be repeated: **<r><y><Enter>**. At end of current processing period, press **<F9>** to start processing repeat samples.	**9.12**
11.	Adding Stats: Go to first sample. **< ↑ >** to Stat entry screen. Type in ID and order tests. **<F9>** to start processing.	**9.13**
12.	Printing Results: **<F2>** "From"/"to": **<starting sample ID><Enter><Ending sample ID><Enter>** Confirm: **<y><Enter>** starts printout.	**9.14**
13.	Starting Over: **<F10><y><Enter>** deletes sample tray.	**9.15**
14.	Exiting Quick-Start: When not processing: **<Esc><y><Enter>**.	**9.17**